Data Standardization as Building Blocks for Artificial Intelligence (AI) in Healthcare

November 30: 12 PM-3 PM/ET
&
December 1: 12 PM-3 PM/ET



**Pat Baird**
**Senior Regulatory Specialist,**
**Head of Global Software Standards at Philips**

Pat Baird works at Philips as the Head of Global Software Standards. Pat likes to think of his job as "Policy Engineering" – understanding the unmet needs (and frustrations) of regulators and developers, and developing standards, whitepapers, and training to meet those needs. His current passion is related to artificial intelligence in healthcare; he is co-chair of multiple AI committees, including the WHO, and is an industry representative on the IMDRF AI committee.

**Dr. Ami Bhatt**
**Director, Outpatient Cardiology and TeleCardiology**
**Massachusetts General Hospital**



Dr. Ami B. Bhatt is the Director of Outpatient Cardiology and TeleCardiology at the Massachusetts General Hospital and an Associate Professor at Harvard Medical School.  She graduated from Harvard College and the Yale School of Medicine and completed her Medicine and Pediatrics Residency at Harvard, her Adult Cardiology Fellowship at Brigham and Women's Hospital and her Adult Congenital Heart Disease and Pulmonary Hypertension Fellowship at the Boston Children's Hospital.

She is an active clinical cardiologist, investigator and educator and founded her first program in virtual care in 2013 and since 2016 she has run the MGH Outpatient Cardiology practice and transitioned cardiovascular care delivery at MGH for over 70,000 patient visits to virtual care in 2020.

She is now creating culturally relevant personalized virtual cardiovascular care delivery models with hospital administration, advocacy organizations, digital health and pharma companies to create collaborations and an environment conducive to agile, patient centered care delivery with high quality outcomes while elevating the patient and clinician experience.

Her research centers on identifying and implementing solutions to barriers to access to cardiovascular and telemedicine care.  The COVID pandemic has amplified the disparities in access to healthcare secondary to disease complexity, health literacy, social determinants of health and risks widening the digital divide.

Dr. Bhatt serves as a medical advisor for digital and telehealth companies from inception, clinical trials and FDA applications to sequential funding rounds. She advocates for policy change and telemedicine legislation with congressional representatives and the GAO.  Dr. Bhatt also leads national telemedicine education via the American College of Cardiology and serves on the Boston Board of the American Heart Association and leads national efforts to address the significant global burden of South Asian Heart Disease. Internationally, she assists countries affected by COVID with an abrupt need to deliver remote care.  Her interest in digital health strategy stems from her belief that state of the art, personalized care can be delivered to individuals in the community, empowering patients and creating stronger clinician-patient partnerships for sustainable health outcomes.

**Hans Buitendijk**
**Director, Interoperability Strategy**
**Cerner Corporation**

For more than 35 years I have been involved in the development of HIT solutions, client consulting on strategic IT planning, health care application development and implementations, large scale business process re-engineering and systems integration, and complex project management, bridging the gap between business process optimization and IT support, as well as improving interoperability across HIT within and across organizations.

I am originally from The Netherlands and am a graduate of the Eindhoven University of Technology in The Netherlands and have a Masters of Science in Management Science and Industrial Engineering.

As Director of Interoperability Strategy at Cerner, I'm primarily focused on establishing and propagating industry standards to enable interoperability across the diverse systems prevalent in health IT.  I represent Cerner in various industry organizations/initiatives to advance interoperability such as HL7, Argonaut, Da Vinci, EHRA, CommonWell Health Alliance, Carequality, and The Sequoia Project to increase adoption of standards-based interoperability.

My current industry initiatives and roles include:

- EHRA
  - Executive Committee Chair
  - Standards & Interoperability Workgroup Chair
  - CARIN Board Member representing EHRA
- ONC HITAC
  - USCDI Task Force Member
- CommonWell Health Alliance
  - STIG Member
- Carequality
  - Carequalty Board Treasurer
  - Carequality Steering Committee Member
- The Sequioa Project®
  - Interoperability Matters Leadership Member
- HL7®

- o Orders & Observations Co-Chair
- o FHIR® Management Group Member
- o LIVD Project Co-Lead
- o V2 Tooling Project Co-Lead
- o V2-to-FHIR Mapping Project Co-Lead
- o Policy Advisory Committee Member
- o US Realm Committee Member
- Argonaut
  - o Steering Committee Member
- Da Vinci Initiative
  - o Steering Committee Vice-Chair
  - o Operating Committee Member

**Lisa Carnahan**
**Associate Director for IT Standardization,**
**Information Technology Laboratory**
**National Institute of Standards and Technology**

Lisa J. Carnahan is the Associate Director for IT Standardization in the Information Technology Laboratory at the National Institute of Standards and Technology (ITL/NIST). She is responsible for developing programmatic strategies for standards engagement, understanding potential standards opportunities in emerging technologies, and promoting the benefits of standards adoption in the federal government and industry. She recently co-authored updates to NIST's key documents for understanding and applying conformity assessment concepts in the federal government.

**Captain Scott Colburn**
**Director - CDRH Standards & Conformity Assessment Program**
**FDA/HHS**

Scott A. Colburn, CAPT, Commissioned Corps of the U.S. Public Health Service, is the Director of the Standards and Conformity Assessment Program at the Food and Drug Administration's Center for Devices and Radiological Health.

In this role, Captain Colburn is responsible for the Center's standards recognition and related development activities in 600+ national and international consensus standards committees. In addition, Scott oversees the program's new Accreditation Scheme for Conformity Assessment (ASCA) Pilot program and the Center's efforts to optimize standards for regulatory use within the International Medical Device Regulators Forum.

Captain Colburn has served in numerous roles in the area of premarket review and voluntary consensus standards development and implementation for medical devices. He is a member of numerous national and international standards organizations and serves on several policy and leadership committees.

**Dale Cyr**
**CEO / Executive Director**
**Inteleos**



Dale is the Chief Executive Officer and Executive Director for Inteleos, the umbrella governance and management organization for the American Registry for Diagnostic Medical Sonography (ARDMS), the Alliance for Physician Certification and Advancement (APCA) and the Point-of-Care Ultrasound Certification Academy (PCA) Councils. Inteleos is an ISO accredited organization with over 120,000 active certificants across 70 countries and delivers healthcare computer-based examinations in 28 countries. Inteleos' global expansion includes addressing healthcare inequality and access to care.

Dale has been an executive within the healthcare certification community for over 20 years and has given numerous lectures and workshops in areas of business and certification throughout the world. Dale is presently Vice-Chair for the American National Standards Institute (ANSI) Board of Directors and is a Past Chair of the Association of Talent Development (ATD) Credentialing Institute and remains on its Board. Dale is also a co-inventor of a patent for a new type of test question and measurement.

Dale has an MBA in finance from the Albers School of Business and Economics, Seattle, WA and also holds the Certified Association Executive (CAE) credential from the American Society of Association Executives (ASAE).



**Jesse M. Ehrenfeld, MD, MPH**
**Immediate Past Chair**
**American Medical Association**



Jesse M. Ehrenfeld, MD, MPH, is a senior associate dean, tenured professor of anesthesiology and director of the "Advancing a Healthier Wisconsin Endowment" at the Medical College of Wisconsin. He also is professor of anesthesiology and health policy at Vanderbilt University. He was elected to the American Medical Association Board of Trustees in 2014.

Dr. Ehrenfeld divides his time among clinical practice, teaching, research and directing a $470-million statewide health philanthropy. He also has an appointment as an adjunct professor of surgery at the Uniformed Services University of the Health Sciences in Bethesda, Md., is a consultant to the World Health Organization Digital Health Technical Advisory Group and has served as special advisor to the 20th U.S. Surgeon General.

Active in the AMA since medical school, Dr. Ehrenfeld has served on the governing councils of both the AMA Resident and Fellow Section and the AMA Young Physicians Section prior to his election to the AMA Board.

In addition to his work with the AMA, Dr. Ehrenfeld has served on the governing boards of the American Society of Anesthesiologists Resident Component, the Massachusetts Medical Society and the Illinois State Medical Society. He also served as speaker of the house of delegates of the Massachusetts Medical Society for six years.

Dr. Ehrenfeld's research, which focuses on understanding how information technology can improve surgical safety and patient outcomes, has been funded by the National Institutes of Health (NIH), the Department of Defense, the Robert Wood Johnson Foundation, the Anesthesia Patient Safety Foundation, and the Foundation for Anesthesia Education and Research.

His work has led to the presentation of more than 250 abstracts, as well as the publication of more than 200 peer-reviewed manuscripts. He is editor-in-chief of the Journal of Medical Systems and has co-authored 18 clinical textbooks that have been translated into multiple languages. Dr. Ehrenfeld has received numerous awards for his research and is a recipient of several prestigious teaching awards.

For the past two decades, Dr. Ehrenfeld has advocated on behalf of lesbian, gay, bisexual, transgender and queer (LGBTQ) individuals. In 2018, in recognition of his outstanding research contributions, he received the inaugural Sexual and Gender Minority Research Investigator Award from the director of the NIH.

Born in Wilmington, Del., Dr. Ehrenfeld is a graduate of Phillips Academy, Haverford College, the University of Chicago Pritzker School of Medicine and the Harvard School of Public Health. He completed an internship in internal medicine, a residency in anesthesiology and a research informatics fellowship at the Massachusetts General Hospital. Board-certified in both anesthesiology and clinical informatics, Dr. Ehrenfeld is a fellow of the American Society of Anesthesiologists and the American Medical Informatics Association.

A combat veteran who deployed to Afghanistan during both Operation Enduring Freedom and Resolute Support Mission, Dr. Ehrenfeld, for his work in capturing and supporting the lives of LGBTQ people, was recognized in 2015 with a White House News Photographers Association award and, in 2016, with an Emmy nomination. Dr. Ehrenfeld and his husband, Judd Taback, have a son, Ethan Ehrenfeld-Taback.



**Bradley Erickson, MD**
**Medical Director for AI**
**Mayo Clinic**

The research interests of Bradley J. Erickson, M.D., Ph.D., include computer-aided diagnosis and the use of computer technologies to extract information from medical images for diagnostic, prognostic and therapeutic purposes. This research includes the development and validation of algorithms that can detect progression, regression or risk of disease, and the prediction of molecular markers from medical images.

Dr. Erickson is also actively developing a system to promote team science, initially pursuing on imaging-focused research, but with connections to genomics, pathology and clinical data.

**Jamie Ferguson**
**Vice President,**
**Health Information Technology Strategy and Policy**
**Kaiser Permanente**

Jamie Ferguson is vice president of health information technology strategy for Kaiser Permanente and is a fellow at the Kaiser Permanente Institute for Health Policy. In addition to serving on the ANSI Board of Directors, Jamie Participates in a number of national and international health IT organizations including Health Level Seven International (HL7), the International Organization for Standardization (ISO), and the World Economic Forum. He is the immediate past chairman of the board of SNOMED International and has served on multiple advisory committees of the U.S. Department of Health and Human Services from 2005 to the present.

Prior to joining Kaiser Permanente, Jamie was a research investigator in molecular biophysics and biochemistry at Yale University, an economist in the Federal Reserve System, a divisional chief information officer at Bank of America, and he had his own business as an independent consultant. Jamie received a bachelor's in molecular biophysics and biochemistry with departmental honors from Yale, and studied computer science and economics at the Massachusetts Institute of Technology.

**Jon Godfread**
**North Dakota Insurance Commissioner**
**North Dakota Insurance Department**

Jon Godfread was elected North Dakota's 22nd Insurance Commissioner on Nov. 8, 2016. In service to the citizens of North Dakota, Godfread has prioritized consumer advocacy, ensuring North Dakotans are better aware of the services offered by the North Dakota Insurance Department beyond industry regulation. He has also worked to restructure the Department for efficient and effective use of tax-payer dollars, along with employee satisfaction. On a national level, Godfread has been an active voice in discussions about insurance regulations including the use of technology, air ambulance service and health care reinsurance. He currently chairs the Innovation and Technology Task Force and the Health Care and Managed Care Committee for the National Association of Insurance Commissioners (NAIC).

Godfread earned a law degree and a Master of Business Administration (MBA) from the University of North Dakota in 2011. He earned his bachelor's degree in business with honors from the University of Northern Iowa in 2005.

**Kerrianne Haresign**
**Senior Manager of Technology & Standards**
**Consumer Technology Association (CTA)**

Kerri Haresign is the Director, Technology & Standards at the Consumer Technology Association (CTA)®. CTA is a U.S. trade association that represents over 2,200 consumer electronics companies and owns and produces CES®, the global stage for innovation.

Haresign is responsible for the management of CTA's Artificial Intelligence Committee, Health, Fitness & Wellness Technology Committee, Video Systems Committee and their associated working groups that develop standards, bulletins and other technical publications. These efforts cover a broad range of

technology subjects including sleep monitoring, physical activity monitoring, consumer stress monitoring, digital therapeutics, AI in Health Care, and DTV Interfaces. Additionally, Haresign manages CTA's Technology Council, a CTO level group bridging the areas of business and technology, exploring topics such as robotics, gesture control, and Ultra HD Interoperability.

Prior to joining CTA in 2016, Haresign served as the Manager for Knowledge Management at the Alliance for Telecommunications Industry Solutions. She is the Vice-President, Board of Director of SES – The Society for Standards Professional and participates in a variety of other standards activities including currently serving as the Vice-Chair of the ANSI Executive Standards Council. Haresign is a proud past recipient of the ANSI Next Generation Award and SES Emerging Professional Award.

**Suzanna Hoppszallern**
**Senior Editor, Data and Research**
**AHA Center for Health Innovation**

Suzanna manages the creation of original research and content for the American Hospital Association aimed at the C-suite and health care executives on health IT and cutting-edge health care topics. She was formerly the Executive Director of Health Technology Assessment, the Society for Healthcare Consumer Advocacy and Society for Social Work Leadership in Health Care at the American Hospital Association. She has a background in technology services consulting and medical research.

**Joe Lewelling**
**Senior Advisor on Content & Strategy**
**AAMI**

Joe Lewelling is the Senior Advisor on Content and Strategy at AAMI. He plans, organizes, and conducts industry conferences and summits on safety, standards, and medical technology regulation. He is also responsible for developing and implementing association strategies vis-à-vis emerging medical technologies and new standards initiatives. Joe has been with AAMI for over 30 years and administered the AAMI sterilization standards program for more than 25 years. In recent years he has led AAMI's new standards work on health IT, artificial intelligence and medical device interoperability. Joe is a member of the ANSI Executive Standards Council and holds master's degrees in Physical Anthropology from the University of Tennessee and in International Business Regulation from George Mason University.

**Phil Lindemann**
**VP of Data & Analytics**
**Epic**

Phil is the VP of Data and Analytics at Epic, where over the last 17 years he has worked with various products to define their development roadmap and strategy.  He has worked on health tech solutions spanning machine learning, data visualization, data quality standards, and real-world evidence generation during his time at Epic.

**Vickie M. Mays, PhD, MSPH**
**Professor, Clinical Psychology**
**UCLA Departments of Psychology and Health Policy and Management, Fielding School of Public Health**

Professor Mays a clinical psychologist and health policy scholar by training.  She is the Director of the UCLA BRITE Center for Science, Research & Policy.  In addition to being, a 15-year NIH funded Center Director, she served as an Assistant Vice Chancellor for Research where she created a Research in Diversity and Equity (RIDE) small grants programs to examine campus climate and is currently a Special Advisor to the Chancellor.   She serves on a number of other boards and committees both within and outside of UCLA.

Professor Mays' research primarily focuses on the mental and physical health disparities affecting racial and ethnic minority populations.  She is particularly known for her research on the impact of race-based discrimination in mental and physical health outcomes, frameworks for the use of social determinants within clinical care settings, use of technology in health care interventions and ethics, equity modeling and the establishment of public trust for health care interventions.  She has a long history of funding not just for her NIH disparity Center but also for her research in mental health services, mental health policy and mental health in integrated care.  Her latest funding at the National Institute of Mental Health is focused on the development of algorithms in the integrated care setting for suicide prevention. As the designer of apps for smoking cessation and a trainer for mhealth, she is interested in the use of technology in health care interventions.  She has expertise in disaster response, recovery and resiliency. She is a certified emergency response team member with the Los Angeles Fire Department.  She worked five years funded by the Kellogg Foundation, to help rebuild and respond to the mental health infrastructure needs after Katrina in New Orleans. Currently she has been involved in the design of a predictive equity model for rolling out the COVID vaccine that is being used in various parts of the U.S.

Dr. Mays is currently a Congressional appointee to the National Committee on Vital and Health Statistics. In her tenure with this committee, she has served as chairperson of the Subcommittee on Populations chaired Ad Hoc Workgroup on Data Access and Use and is currently Co-Chairing a Workgroup on Social Determinants of Health and Sexual Orientation and Gender Identity.  Dr. Mays serves on the Executive Subcommittee, Subcommittee on Privacy, Confidentiality and Security and the Ad Hoc Review of ACA for the Standards Subcommittee.

**Bakul Patel**
**Director, Digital Health Center of Excellence**
**FDA**

Bakul Patel is the Director for Digital Health Center of Excellence, at the Food and Drug Administration (FDA). Mr. Patel is responsible for providing leadership, development, implementing, execution, management and setting strategic direction and regulatory policy and coordinate scientific efforts for digital health, software and emerging technologies.

Mr. Patel, in 2013, created the term "software as a medical device" (SaMD) and under his leadership the International Medical Device Regulators Forum (IMDRF) established the globally harmonized definition of SaMD. Mr. Patel subsequently led global regulators at IMDRF to create and author the globally harmonized regulatory framework for SaMD. The concepts, principles and vocabulary created in harmonized regulatory framework has been used as a foundation and adopted by medical device

regulatory bodies in the European union, Japan, Canada, Brazil, Australia and in the USA by US-FDA. Mr. Patel is currently leading the effort for the agency in developing an innovative software precertification program to reimagine a pragmatic regulatory approach for Digital health that that aims for patients and providers to have timely access to safe and effective digital health products.

Prior to joining FDA, Mr. Patel held key leadership positions in several sectors including telecommunications industry, semiconductor capital equipment industry, wireless industry and information technology industry. His experience includes Lean Six Sigma, creating long and short-term strategy, influencing organizational change, modernizing government systems, and delivering high technology products and services in fast-paced, technology-intensive organizations. 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.

**Don Rucker, MD**
**Chief Strategy Officer**
**1upHealth**
**Former National Coordinator ONC**

Dr. Don Rucker is Chief Strategy Officer at 1upHealth which provides scalable serverless FHIR data pipelines that feed the modern data world.  He recently served as the National Coordinator at ONC where he led the writing of the ONC 21st Century Cures Act Interoperability Rule giving patients control of their medical records using apps of the patient's choosing.   Dr. Rucker pioneered the policy building the HL7 Bulk FHIR standard which enables effective use of EHR data for "big data" analytic and operational tools.   He co-developed the world's first Windows based EMR and continued with transformative work in computerized physician order entry as well as leading policy for health information exchange.   Dr. Rucker has practiced emergency medicine for 30 years and is currently on the adjunct faculty at the Ohio State University Dept of Emergency Medicine.  He is a graduate of Harvard College, the University of Pennsylvania School of Medicine and is board certified in emergency medicine, internal medicine and clinical informatics.  He has an MBA and an MS in medical computer science, both from Stanford.

**Berkman Sahiner**
**Senior Biomedical Research Scientist**
**Office of Science and Engineering Laboratories**
**FDA**

Berkman Sahiner is a senior biomedical research scientist with the Office of Science and Engineering Laboratories at the FDA. He holds a PhD in electrical engineering and computer science from the University of Michigan, Ann Arbor. Before joining the FDA, he was an Associate Professor with the Department of Radiology at the University of Michigan. At the Division of Imaging, Diagnostics and Software Reliability at the FDA, he performs research related to the evaluation of medical imaging and computer-assisted diagnosis devices, including devices that incorporate machine learning and artificial intelligence. He has authored over 130 peer-reviewed journal publications, and is a fellow of the Society of Photo-optical Instrumentation Engineers (SPIE) and American Institute for Medical and Biological Engineering (AIMBE). His interests include machine learning, image perception, clinical study design, and performance assessment methodologies.

**Mary Saunders**
**VP, Government Relations and Public Policy**
**ANSI**

Mary Saunders is vice president, government relations and public policy, at the American National Standards Institute (ANSI). In this position, Ms. Saunders serves as ANSI's spokesperson and liaison to federal, state, and local government agencies and to Congress and congressional staff. She supports the activities of the ANSI National Policy Committee and the ANSI Government Member Forum, working with the members of these committees to develop and advance the Institute's positions and policies at all levels of government. In turn, she identifies and communicates to ANSI stakeholders emerging issues of importance for the standards and conformity assessment community.

Prior to joining ANSI in 2017, Ms. Saunders was the associate director for management resources for the U.S. Department of Commerce's National Institute of Standards and Technology (NIST), and served as a vice chair on the ANSI Board of Directors. She is responsible for all NIST-wide institutional support and administrative offices and their functions, including: workforce management, information technology and services, safety and environmental management, facilities maintenance and construction, accounting and finance, acquisitions and grants management, budget formulation, strategic planning, and emergency response. Ms. Saunders previously served as the director of NIST's Standards Coordination Office. In this capacity, she represented NIST and its significant interests in the standards and conformity assessment community, advising the NIST director and other officials throughout the administration on policy and strategy as they relate to the federal government's role in standardization.

She also served as Deputy Assistant Secretary for Manufacturing and Services in the International Trade Administration, managing more than 200 industry specialists, economists and international trade experts. In that capacity, she helped strengthen the competitive position of U.S. industries globally by coordinating Commerce Department strategies, policies, and programs with U.S. industries in mind.

ANSI is a not-for-profit membership organization that brings together organizations from both the private and public sectors dedicated to furthering U.S. and international voluntary consensus standards and conformity assessments. ANSI accredits national standards developing organizations and approves American National Standards. ANSI is also actively engaged in accrediting programs that assess conformance to standards, with programs for all types of certification and verification bodies, including those for products/products/services, personnel, and greenhouse gas emissions. It is the sole U.S. representative to the International Organization for Standardization (ISO) and, via the U.S. National Committee, the International Electrotechnical Commission (IEC). ANSI is also a member of the International Accreditation Forum, the Pacific Area Standards Congress, and the Pan American Standards Commission.

**Christina Silcox**
**Digital Health Policy Fellow**
**Duke-Margolis Center for Health Policy**



Christina Silcox is the Digital Health Policy Fellow at the Duke-Margolis Center for Health Policy, working on policy solutions to advance innovation in health and health care and improve regulation, reimbursement, and long-term evaluation of medical products, with a focus on digital health.

Dr. Silcox's portfolio includes multiple areas in digital health policy and real-world evidence, with a focus on medical devices. Currently, she is concentrating on challenges to regulating and adopting of artificial intelligence-enabled software as a medical device, using mHealth to collect real-world data, and characterizing real-world data quality and relevancy. Her projects have included the use of patient-generated health data in medical device evaluations, the exploration of value-based payments for medical devices, and the convening the National Evaluation System for health Technology (NEST) Planning Board.

Before she joined Duke-Margolis, Dr. Silcox was a senior fellow at the National Center for Health Research, focused on federal regulation of and policies for medical products. She earned a M.S. from the Massachusetts Institute of Technology (MIT) in Electrical Engineering and a Ph.D. in Medical Engineering and Medical Physics from the Harvard-MIT Division of Health Sciences and Technology (HST).

**Yanshan Wang**
**Assistant Professor and Vice Chair of Research, Health Informatics**
**Department of Health Information Management**
**School of Health and Rehabilitation Sciences, University of Pittsburgh**



Yanshan Wang, PhD, FAMIA is vice chair of research and assistant professor of health informatics with a primary appointment in the Department of Health Information Management, School of Health and Rehabilitation Sciences, and a secondary appointment in the Department of Biomedical Informatics, School of Medicine, at the University of Pittsburgh. He joined Pitt in June 2021 from the Mayo Clinic, where he still holds an adjunct Assistant Professor position. His research centers on clinical natural language processing using electronic health record data.