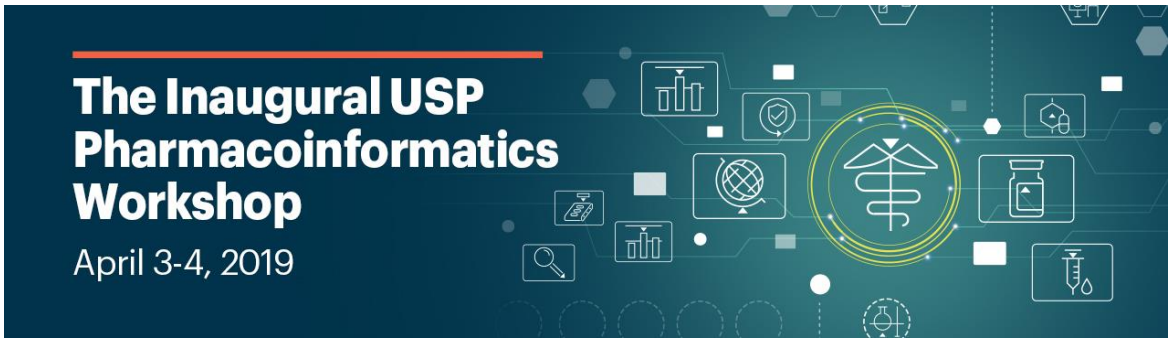


The Inaugural USP Pharmacoinformatics Workshop

April 3-4, 2019

Speaker Biographies & Abstracts (listed alphabetically)

Shantanu Agrawal, Ph.D.
President and CEO of the National Quality Forum
Washington, DC

Shantanu Agrawal, MD, MPhil, is president and CEO of the National Quality Forum (NQF). A board-certified emergency medicine physician who has worked in both academic and community settings, Dr. Agrawal is the former deputy administrator for the Centers for Medicare & Medicaid Services (CMS) and director of one of its largest centers, the Center for Program Integrity (CPI).

At CMS, Dr. Agrawal led an effort to improve the physician experience with Medicare by working to minimize the administrative tasks with which doctors contend. He also was one of the main architects of CMS's strategy and action plan to address the national opioid misuse epidemic. His main focus at CPI was improving healthcare value by lowering the cost of care through the detection and prevention of waste, abuse, and fraud in the Medicare and Medicaid programs. From 2012 through 2014, CPI's prevention efforts saved Medicare and Medicaid over $50 billion.

Dr. Agrawal previously served as CPI's chief medical officer and was instrumental in launching new initiatives in data transparency and analytics, utilization management, assessment of novel payment models, and stewarding a major public-private partnership between CMS and private payers, the Health Care Fraud Prevention Partnership.

In addition to leading NQF, Dr. Agrawal is co-chair of the Department of Veterans Affairs Secretarial Fraud, Waste, and Abuse Prevention Advisory Committee and serves on the board of the Grameen Foundation, the Presidential Advisory Council of Brown University's School of Public Health, and the editorial board of the journal Population Health Management. He is an adjunct senior fellow at the Leonard Davis Institute of Health Economics at the University of Pennsylvania and an associate clinical professor of emergency medicine at the George Washington University Hospital.

Dr. Agrawal has testified numerous times before Congress and is a frequent national speaker on healthcare and cost. He is a well-published author with articles in *Journal of the American Medical Association*, *New England Journal of Medicine*, *Annals of Emergency Medicine*, among others.

Prior to joining CMS, Dr. Agrawal was a management consultant at McKinsey & Company, serving the senior management of hospitals, health systems, and biotech and pharmaceutical companies on projects to improve the quality and efficiency of healthcare delivery. He also worked for a full-risk, capitated delivery system as its leader for clinical innovation and efficiency.

Dr. Agrawal completed his undergraduate education at Brown University, medical education at Weill Medical College of Cornell University, and clinical training at the Hospital of the University of Pennsylvania. He has a master's degree in social and political sciences from Cambridge University.

Presentation
Keynote
Wednesday, April 3, 2019, 9:15 – 10:00 a.m.

Steven Bird
Waters Informatics
Boston, MA

Steve Bird has over 30 years of experience in the Life Science industry as an engineer, IT professional and strategic market leader, and is currently the Director of Informatics Strategic Marketing at Waters Corporation. In his current role he is accountable for the Informatics software strategy working directly with our Global Key Account customers, partners and industry bodies in the life, materials and food sciences industry. Steve is a technology professional skilled in Product Lifecycle Management, Biotechnology, Market Research, Management, Product Marketing, Platform Technologies and Cloud Computing. Throughout his career at Waters he has held numerous positions in Product Management and Strategic Partner Relations Management, instrumental in on boarding key technologies and partners. He received his B.S. in Information Technology at the University of Massachusetts Lowell.

Presentation
Standardizing Data and It's Context from Planning Through Capture to Facilitate Consumption and Analysis
Thursday, April 4, 2019, 1:40 – 2:00 p.m.

The way people create and manage analytical data has evolved from simple measurement capture to a wide variety of secondary uses. These combine the measurements, meta data about the measurements and even data from what might have been thought of as unrelated areas to derive answers for questions about unexpected results, business process optimizations and business insights that by themselves are not obvious by simply looking at the empirical measurements. With this has risen the need for vendor neutral data to support inter-operation between data systems and support for large data lakes of information. Waters will explain its approach to vendor neutral data and our support of the Allotrope Foundation.

Allotrope Foundation is an international consortium of pharmaceutical and biopharmaceutical companies created to revolutionize the way we acquire, share and gain insights from scientific data, through a community and the framework for standardization. The Foundation draws from the breadth and diversity of expertise of subject matter experts across over 60 member companies, vendors and academic institutions. Through a strong collaborative culture, the Allotrope Community has partnered to deliver a "real world" solution to address the root cause of common challenges in the scientific data landscape. This initiative has led to breakthroughs that enhance data integrity, reduce manual effort, enable seamless interoperability, and drive the realization of the full value of scientific data.

The Allotrope Framework implements a single, universal data format (Allotrope Data Format, ADF) and addresses data quality at the source through ontologies and data models that provide the standard language for describing the equipment, processes, materials, and results covering a broad range of techniques and instruments. The ADF is now established as the most easily extensible instrument, technique, vendor and platform agnostic standard format for data. In addition, it is the first format that integrates semantic standards and capabilities with the data storage, enabling an unprecedented connectivity in the bio-pharmaceutical domain.

Following an overview of Allotrope Foundation and the Framework, this will feature examples that demonstrate how the Allotrope Framework is being implemented in solutions developed by Allotrope Partners, which are the cornerstone of adoption across the industry and are powering our digital transformation. TetraScience joined Allotrope Partner Network in 2017 and since then has been one of the most active partners and contributors to Allotrope framework.

	TetraScience is a Data Integration and Insights Platform for the Life Sciences. With TetraScience, laboratories connect critical information sources from instruments and lab systems to a cloud-based data platform. Data is centralized and standardized and available to downstream targets resulting in improved data management and streamlined process. TetraScience is currently leveraging its Data Integration Platform to collect, standardize and centralize the siloed data sets from scientific instruments, CRO/CMO, software databases. Based on this platform, TetraScience is actively working with Allotrope and Waters together to create the first Allotrope Data Format converter for Waters Empower data. This community project will lead to the various uses cases around semantic search, seamless interoperability, data analytics, and many others.

Donna Bohannon, R.Ph
Senior Scientific Liaison, HealthCare Quality and Safety
USP
Rockville, MD

Donna Bohannon is the senior scientific liaison for the Healthcare Quality and Safety Expert Committee (HQS EC) at United States Pharmacopeia (USP). USP is a non-profit organization that establishes standards to help ensure medicine is of the highest quality from the time it's manufactured until the moment someone takes it. She is currently working with the USP HQS EC to develop standards to support patients and practitioners when documenting allergies and intolerances, compounded preparations and formulary classification in electronic environments to support safe medication use. As a former medication safety officer in the hospital setting, she has been involved in EHR implementation, smart pump integration and the development of databases that support voluntary reporting and analysis of medication errors. Additionally, she investigated monitored and developed policy and procedures to mitigate adverse drug events related to the use of digital systems to support safe medication use. To supplement her clinical background as a pharmacist, she attained a Master of Science in Health Informatics Administration to support the work of the expert committee.

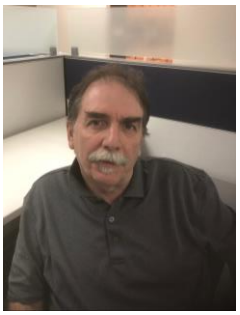
Presentation
Introduction to USP and Digital Platform
Wednesday, April 3, 2019, 8:45 – 9:15 a.m.

Richard Boyce, Ph.D.
Associate Professor of Biomedical Informatics and Clinical and Translational Science
University of Pittsburgh Clinical and Translational Science Institute
Pittsburgh, PA

The use of informatics to support safe and effective medication therapy for older adults has been Dr. Boyce's primary interest since the early stages of his research career. He has more than 15 years of research experience at the intersection of in informatics, clinical research, and pharmacoepidemiology. He was the principal investigator of an R01 project funded by the National Library of Medicine that studied a novel approach to addressing gaps in drug-drug interaction evidence (R01 LM011838). He currently directs the Informatics Core for a U54 grant (U54 AT008909) studying natural product – drug interactions that is funded the National Center for Complementary and Integrative Health. His publication record includes more than 40 peer reviewed papers at the intersection of medication safety, informatics, and decision support. Dr. Boyce led development of a Word Wide Web Consortium (W3C) Community Group report that suggests a minimum information model for describing clinically oriented information about potential drug-drug interactions. He also is currently leading the effort of the HL7 Clinical Decision Support Workgroup project to develop an implementation guide that specifies how to provide sharable PDDI CDS services to electronic health record (EHR) systems using the minimum information model, HL7 FHIR, CDS Hooks, and CQL.

Presentation
Applied Clinical Informatics – Drug Interactions
Wednesday, April 3, 2019, 10:30 – 11:00 a.m.

Identifying potential drug-drug interactions (PDDIs) during the care process is important to ensure patient safety and mitigate risk. However, the body of evidence about PDDIs is overwhelming and dynamic. As it is impossible for clinicians to keep up with the PDDI evidence base, drug experts generate summaries of PDDI evidence from primary sources. These summaries bring PDDI knowledge to clinicians in the form of published drug information compendium, clinical decision support rules, and interaction checking applications. However, there are currently no broadly accepted standards to guide these experts in the organization, content, and presentation of PDDI information. In this talk, I will provide a brief introduction to a suggested minimum information model for information about potential drug-drug interactions. The information model consists of non-ambiguous definitions for 10 core information items, and 8 detailed best practice recommendations related to the 10 core information items. Adoption of the recommendations by developers of PDDI knowledge artifacts will improve the usefulness of the artifacts within clinical workflows. Intended downstream applications include clinical decision support, drug product label enhancement, cohort identification, and other activities relevant to protecting patients from harm from drug interactions. Focusing on clinical decision support, I will describe current research that integrates the information model with HL7 FHIR and CDS Hooks to create a sharable service that coordinates drug knowledge and alerts during the medication ordering process. In addition to standardizing care, sharable service-based PDDI CDS could help disperse the burden of optimizing alerts and maintaining drug knowledge.



Lawrence Callahan
FDA
Bethesda, MD

Larry Callahan obtained his Ph.D. in Chemistry from the University of Chicago. He was previously employed at FDA, NIH and the United States Pharmacopiea (USP). He has been involved in Nucleic Acid, HIV, tuberculosis research and the development of analytical methods for biotechnology-derived products. He also has been responsible for the management and development of chemical/biological databases for the National Institute of Allergy and Infectious Disease, National Library of Medicine, National Cancer Institute and the Food and Drug Administration

Larry is currently responsible for the development and management of the FDA's Global Substance Registration System (G-SRS). The goal of the GSRS is to define all substances in FDA regulated products and assign a Unique Ingredient Identifier (UNII) to each substance and create meaningful relationships between substances. These relationships include impurities, metabolites, metabolic enzymes, transporter and target proteins along with specifications for active substances and LADMER data for substances and products. The G-SRS also links substances to products, applications clinical trials and adverse events.

Drs. Callahan, Herman Diederik, Frank Switzer were the primary editors of the ISO 11238 Standard for defining substance and with of the Dutch Agency and the EMA are the primary editors of ISO TS-19844 document which is the implementation guide for defining all substances in medicinal products. Dr. Callahan is also the FDA lead on the Global Ingredient Archival System (GInAS) project, which attempts to integrate regulatory, toxicological, and clinical information on all substances in medicinal products.

Presentation
Global Substance Registration System (G-SRS)
Thursday, April 4, 2019, 3:00 – 3:30 p.m.

Steven Emrick
Senior Product Manager, HealthCare Quality and Safety
USP
Rockville, MD

Steve Emrick currently works in the Documentary Standards team at USP, as the lead of Informatics and Digital Product Development, a newly formed enterprise-wide initiative that aims to provide informatics capability to USP's wide array of Science and stakeholder interests. The goal of this infrastructure is to maximize the public health impact of USP standards in digital environments, tailor product offerings with end user need, as well as coordinate with other private, professional, and regulatory stakeholders who are working to solve informatics challenges across the industry.

Before coming to USP, Steve spent almost 10 years at the National Library of Medicine, most recently as the head of the Terminology Quality & User Services team. This team supports implementation, customer support, and data quality of many NLM vocabulary products and tools, such as Unified Medical Language System, RxNorm, SNOMED CT, the Value Set Authority Center, and AccessGUDID.

Steve graduated from Juniata College in Huntingdon, PA, with a degree in Molecular Biology and a minor in French. After graduating, Steve served for 5 years in the US Army as a Signals Intelligence Analyst and Korean Linguist. Steve served in the 2nd Infantry Division, as well as the 532nd Military Intelligence Brigade at various duty stations throughout the Korean Peninsula. He currently resides in Silver Spring, MD with his wife and three children.

Presentation
Introduction to USP and Digital Platform
Wednesday, April 3, 2019, 8:45 – 9:15 a.m.

Frank Federico, Ph.D.
Executive Director
Institute for Healthcare Improvement (IHI)
Boston, MA

Frank Federico, RPh is a Vice President, Senior Safety Expert, Institute for Healthcare Improvement (IHI) where he works in the areas of patient safety, and application of reliability principles in health care. He is faculty for the IHI Patient Safety Executive Development Program and has co-chaired a number of Patient Safety Collaboratives. He is past Chair of the NCCMERP Council. Prior to joining IHI, Mr. Federico was the Program Director of the Office Practice Evaluation Program and a Loss Prevention/Patient Safety Specialist at Risk Management Foundation of the Harvard Affiliated Institutions, and Director of Pharmacy at Children's Hospital, Boston. He has authored numerous patient safety articles, co-authored chapters in Achieving Safe and Reliable Healthcare: Strategies and Solutions, as well as other publications, and is an Executive Producer of "First, Do No Harm, Part 2: Taking the Lead.". He coaches teams and lectures extensively, nationally and internationally, on patient safety.

Presentation
Keynote Speaker
Thursday, April 4, 2019, 8:30 – 9:15 a.m.

The intersection of patient safety and technology
Description: technology is playing a greater role in our lives and particularly in health care. However, technology presents both advances and new opportunities for harm. The expectation that technology will solve the problems associated with lack of patient safety can be summarized by the expectation “If only we had…” In this session, faculty will share lessons learned with the application of technology in health care. Foundational to improvement is the teamwork needed to build safe systems and developing a culture that supports transparency, psychological safety and a leaning system that guides clinicians to learn from what works well and what does not.

Objectives
Describe how technology can advance improvement in health care such as reduction of medication errors and improvement of diagnosis
Discuss how technology can be used to develop predictive models to identify patients at greatest risk of medication-related harm
Discuss the importance of a culture of safety in the technology age.

Elaine Johanson
Director (Acting)
Office of Health Informatics
Washington, DC

Since July of 2016, Elaine Johanson has served as the Director of Health Informatics within the Office of the Chief Scientist at the Food and Drug Administration. In this position, she utilizes non-traditional mechanisms to share FDA data and to engage external experts in evolving areas of regulatory science. In addition, she facilitates agency-wide participation in international health data and terminology standards, leads the identification and curation of substance information and the exchange of product labeling information for FDA. Public facing examples of activities under Elaine Johanson's leadership include:

OpenFDA - An FDA open data platform that has made it easier for researchers, scientists and developers to access publicly available FDA data related to drug adverse events, drug labeling, medical devices, and food recalls. To date, there have been more than 20 million API calls, more than 6,000 registered users, 21,000 connected systems, and dozens of new software applications devoted to making FDA data and analysis available to a wider audience.

PrecisionFDA - A collaboration space for genomics researchers around the world to work with FDA scientists to advance regulatory science through competition, sharing of tools, testing and comparision of tools, and expert dialogue. PrecisionFDA has over 3,000 members, and offers: (1) 42 terabytes of reference data, (2) an extensive library of NGS analysis tools and applications, (3) computational resources, (4) a discussion forum (5) expert blog posts, (6) app-a-thons, and (7) community challenges which promote crowd-sourced scientific innovation and advancement.

Healthy Citizen - A new exploratory initiative piloting in 2019 to provide cross-cutting FDA product information directly to healthcare providers and citizens by making tools available for use via healthcare portals. This project will enable the FDA to, (1) disseminate recall information, consumer complaints, and adverse event trends to the public in a consistent, targeted and timely manner, (2) collect and analyze de-identified citizen data related to usage of FDA-regulated products, and (3) send targeted invitations for relevant clinical and regulatory research and trials to citizens that fit the profile of the studies.

With thirty-three years' experience in information technology (IT) and health informatics, including fourteen years as a senior, strategic leader, Elaine Johanson has led an office of as many as 415 IT personnel, scientists and public health specialists. She has managed a portfolio of projects in excess of $400 million and has extensive knowledge of scientific computing, health informatics, genomics and next generation sequencing (NGS), cloud computing, crowd-sourcing, international data standard management, data harmonization, data analysis, strategic planning, software development, infrastructure operations, budget formulation and execution, human resources management, governance, project, risk, program and portfolio management. She has presented at and facilitated meetings with a wide range of internal and external stakeholders including, scientists, regulators, foreign dignitaries, congressional personnel, senior executives, and industry representatives.

Presentation
Precision FDA
Wednesday, April 3, 2019, 2:45 – 3:15 p.m.

Michael Levy, M.Sc., M.B.A.
Vice President, Head of USP's Quality Institute, and Head of Research & Innovation
USP
Rockville, MD

Michael Levy is Vice President, Head of USP's Quality Institute, and Head of Research & Innovation. The Quality Institute focuses on generating a rigorous evidence base for global discussions on public and regulatory policy reforms to advance quality of medicines. The Institute strives to improve public health outcomes and provide the rationale for investments in quality.

Research & Innovation is the scientific team responsible for the identification, assessment, and as appropriate, incubation of emerging technologies and capabilities relevant to USP's standard-setting processes and allied programs.

Mr. Levy's diverse background includes shaping public policy through advocacy, counseling biopharmaceutical and healthcare regulatory executives and staff as a management consultant, and providing deep scientific and technical expertise to academic and industry researchers. He previously served as Deputy Vice President, Science & Regulatory Advocacy, at the Pharmaceutical Research and Manufacturers of America (PhRMA), where he shaped the drug development and regulatory review processes—with an emphasis on using non-traditional data and advanced analytics to inform clinical trial design and regulatory decision making. Mr. Levy also served as an Associate Principal at McKinsey & Company, where he supported biopharmaceutical companies and regulators on a broad set of topics in Research and Development and technology enablement. Earlier in his career, Mr. Levy was part of the team that sequenced Human Chromosome XIV as part of the Human Genome Project, and was lead bioinformatician in a bioinformatics start-up.

Mr. Levy earned his Masters of Business Administration Degree from Cornell University's Johnson Graduate School of Management, and his Master of Science and Bachelor of Science degrees from Concordia University in Montreal, Canada.

Welcome
Wednesday, April 3, 2019, 8:30 – 8:45 a.m.

Edwin Lomotan, Ph.D.
Chief of Clinical Informatics
Agency for Healthcare Research and Quality (AHRQ), Center for Evidence and Practice Improvement
Rockville, MD

Edwin Lomotan, MD, FAAP, FAMIA is a Medical Officer and Chief of Clinical Informatics for the Health IT Division in AHRQ's Center for Evidence and Practice Improvement. He currently leads AHRQ's clinical decision support (CDS) initiative, which aims to advance evidence into practice through CDS and to make CDS more shareable, standards-based, and publicly-available. Dr. Lomotan is board-certified in pediatrics and clinical informatics. He received his medical degree from the University of Pittsburgh and completed his pediatrics residency and informatics fellowship at Yale University. He also spent several years in community pediatric practice in Connecticut before joining Federal service in 2010.

Presentation
Interoperable Clinical Decision Support for Pain Management
Wednesday, April 3, 2019, 2:00 – 2:30 p.m.

The Agency for Healthcare Research and Quality (AHRQ) has an ambitious ongoing initiative with two broad aims: to advance research evidence into clinical practice through computer-based, clinical decision support (CDS) and to make CDS more shareable, standards-based, and publicly-available. This initiative has several components, including a patient-centered learning collaborative, prototype infrastructure for developing and sharing standards-based CDS, grant funding opportunities, and an evaluation. The prototype infrastructure, called CDS Connect, has several tools to help health care systems and health information technology developers build, implement, and share CDS so that the overall process – across health care systems – is more efficient. AHRQ, in collaboration with the MITRE Corporation, demonstrates the CDS Connect infrastructure and tools through use cases. In 2018, AHRQ developed the Pain Management Summary in a use case focused on chronic pain and opioids. The Pain Management Summary is a SMART on FHIR application that functions as a "dashboard," which consolidates patient-specific, pain-related information normally scattered throughout a patient's electronic health record into a single view. In this presentation, Dr. Lomotan will describe AHRQ's overall CDS initiative, with a special focus on the Pain Management Summary as an example of ongoing efforts within the CDS Connect project.

Stephen Mullenix, B.S. Pharm, R.Ph.
Senior Vice President of Public Policy and Industry Relations
National Council of Prescription Drug Programs (NCPDP)
Denver, CO

Steve Mullenix joined the National Council for Prescription Drug Programs (NCPDP) in June of 2009 and currently serves as Senior Vice President of Public Policy & Industry Relations. Prior to accepting his current position, Steve served as Director of Professional & Trade Relations for Covidien/Mallinckrodt Pharmaceuticals. Steve also served as Vice President of Managed Care & Professional Services during a ten year period with the national pharmacy franchise organization, Medicap Pharmacies, Inc. He is the former Executive Vice-President of the national drug utilization review and pharmacy consulting company, Q-A, Inc. Steve also served as Vice-President and Chief Operating Officer for the Iowa Pharmacy Association (IPA) and its for-profit subsidiary, PNI.

Mr. Mullenix began his career in community and hospital pharmacy serving for more than a decade as director of pharmacy at a regional health system including consultancy of both inpatient and outpatient addiction treatment services. Since that time he has served in a number of research, consultant, teaching and administrative capacities and now represents NCPDP in the areas of public policy, and professional and industry relations both nationally and internationally. He has authored or been quoted in a number of professional publications, has provided Congressional testimony, has received numerous professional awards and is a frequent speaker on topics such as healthcare quality and safety, medication therapy management, pharmacy standards and health information technology.

Steve is a graduate of the University Of Iowa College Of Pharmacy.

Presentation
Applied Clinical Informatics – Data standards in e-prescribing
Wednesday, April 3, 2019, 11:15 – 11:45 a.m.

NCPDP, as an ANSI-Accredited Standards Development Organization has for over the last 41 years of its existence been committed to the standardized exchange of healthcare information to improve patient outcomes. During this time particular emphasis has also been placed on improved efficiency, reduced provider burden and most importantly, improved patient safety. This presentation will focus on NCPDP, the organization, its processes and priority initiatives. In addition, the ongoing development of two of the more significant Real Time Communication Standards authored by NCPDP, (i.e. Telecom and SCRIPT) will be explained in some detail including new emerging capabilities within the clinical space.

Richard Parrish, II, BSPharm, PhD, FCCP, BCPS
USP Affiliation: Co-chair, USP Exchange of Compounded Preparation Information in Health IT Systems Expert Panel

Dr. Richard Parrish is Director and Chief Pharmacist at St. Christopher's Hospital for Children, Philadelphia, and Clinical Associate Professor at Virginia Commonwealth University School of Pharmacy. He graduated with a B.S. in Pharmacy from The Ohio State University, completed a Master of Science from Auburn University, and earned a PhD from the University of Minnesota. In 2015, Richard published a series of papers appearing in *Pharmacy (Basel)* outlining the need for encoding compounded drug preparations, identified priorities for creating a separate and distinct prescription generation and medication management system designed for children's pharmacotherapy, and proposed creation of an electronic repository for compounded drug preparations that would articulate with and populate other drug databases and platforms. He was invited last year to present on trends and priorities in compounded pediatric preparations at USP's Inaugural Workshop on Evolution and Advances in Compounding, and published this work in the *International Journal of Pharmaceutical Compounding*. Richard was selected as a 2017 Distinguished Alumnus from The Ohio State University College of Pharmacy.

Presentation
Reducing Medication Errors from the Electronic Prescription Transmission – Encoding Compounded Drug Preparations
Thursday, April 4, 2019, 10:30 – 11:00 a.m.

This presentation will outline progress to-date from the Expert Panel on the Exchange of Compounded Drug Preparation Information in Health IT Systems. The work plan development for the group is focused on proposing a set of rules that govern how compounded drug preparations are encoded and exchanged in patient electronic health records, pharmacy systems, e-prescribing, and other Health IT systems where medication information related to the patient is needed. Included in this work are identifying authorized monographs, surveying provider and end-user groups for information about data specificity during e-prescribing, and generating guidelines for development of a compatible data model for clinical formulation identifiers. This presentation will also discuss how evolving nomenclature-encoding standards are part of a quality assurance system for comprehensive medication management in children, thereby minimizing medication errors across the continuum of care.

Josh Peterson, Ph.D.
Associate Professor of Biomedical Informatics and Medicine
Vanderbilt Medical Center
Nashville, TN

Josh Peterson, MD, MPH is Associate Professor with appointments in the Departments of Biomedical Informatics and Medicine at Vanderbilt University Medical Center (VUMC), and an internist with an active primary care practice. Dr. Peterson's research interests are in precision medicine with a focus on translating genomic technologies to routine clinical care. Over his 20-year career in clinical informatics, he has led the design and implementation of clinical decision support systems to improve drug safety. Currently, he leads implementation of one of the largest pharmacogenomics implementations in the US – PREDICT. He serves as a principle investigator for an NIH funded project to simulate the clinical impact and cost-effectiveness of sequencing large populations over their lifetime. He also leads two NIH-sponsored genomic medicine consortia: eMERGE (Electronic Medical Records and Genomics) where he is principle investigator of the Coordinating Center and co-Chair of the Outcomes Workgroup and IGNITE 2 where he serves as principle investigator for the VUMC site.

Presentation
Personalized Medicine and Pharmacogenomic Data
Thursday, April 4, 2019, 11:00 – 11:30 a.m.

The use of pharmacogenomic data to tailor therapeutics has advanced considerably with the decreasing cost and breadth of genetic testing. Scientific and implementation challenges are being addressed and guidelines for use of the data is well published. However, the field is still hindered by a number of data standard and clinical informatics issues. The presentation will review data pipelines from testing machine to bedside, existing and emerging pharmacogenomic data standards, and successful deployments of scalable clinical decision support. It will also touch on the landscape of NIH-funded projects pioneering large scale genetic population screening, and review the remaining policy challenges to making pharmacogenomic technologies accessible to all.

Matthew Pickering
Senior Director, Research & Quality Strategies
Pharmacy Quality Alliance (PQA)
Alexandria, VA

Dr. Matthew K. Pickering serves as the Senior Director of Research and Quality Strategies at the Pharmacy Quality Alliance (PQA). In this role, he identifies needed studies to further validate the impact of PQA's measures on improving patient care, reducing overall healthcare spending, and filling recognized gaps in performance measurement. Dr. Pickering is also responsible for coordinating PQA research and demonstration project portfolios. He works closely with the PQA research team to implement high quality, responsive, and timely activities that support PQA research functions and internal operations. Dr. Pickering also serves as PQA's Research Fellowship Director and manages all aspects of the program.

Prior to joining PQA, Dr. Pickering completed a two-year Postdoctoral Fellowship at the University of Maryland, School of Pharmacy where he utilized large clinical and claims datasets to conduct a series of research projects investigating Alzheimer's disease and related dementia. He also leveraged large data assets for the derivation and testing of healthcare quality performance measures. Prior to joining the University of Maryland, Dr. Pickering received his PharmD from East Tennessee State University and has also completed a Fellowship in Medical Communications and Drug Information at the Therapeutic Research Center. Dr. Pickering's research activities include comparative effectiveness research, patient-centered outcomes research, and quality performance measurement.

Presentation
Quality Measurement and Informatics
Thursday, April 4, 2019, 9:45 – 10:15 a.m.

The United States (US) healthcare system is moving from a fee-for-service payment model to one of value-based purchasing, with provisions set forth in legislation for accountable care organizations, medical homes, bundled payments, and a focus on quality. Measurement of quality is expanding rapidly throughout the US healthcare system. Quality in healthcare is most often measured through the use of performance indicators, also known as performance measures. The Centers for Medicare and Medicaid (CMS) uses quality measures to evaluate Medicare Part C and Part D plans with the Star Ratings System. Medicare Part D ratings include measures for medication use under the domain of patient safety and accuracy of drug pricing. Within the Stars Program, CMS publicly reports data an MTM-specific quality measure, which evaluates the percentage of MTM-eligible beneficiaries who received a comprehensive medication review. CMS intends to adopt further process and outcomes measures for MTM once they are developed and endorsed. To accomplish this, new data standards are need to ensures the accuracy, completeness, and appropriateness of patient interactions, written communications to patients and providers, and MTM encounter records.

During this session, participants will be able to:

- Discuss the current state of medication-use measures and where we are going in terms of quality performance measurement;
- Recognize the stakeholders involved in measure development and implementation; and
- Describe the challenges and opportunities for building novel medication management measures that require new data standards

Rebecca Racz, Pharm.D.
Pharmacologist
FDA/CDER
Silver Spring, MD

Dr. Rebecca Racz has worked for the US FDA's Center for Drug Evaluation and Research (CDER) as a pharmacologist for 3 years, leading multiple initiatives to predict adverse events, identify secondary drug targets, and evaluate adverse event mechanisms. She is the Principal Investigator on a Research Collaboration Agreement with a commercial predictive analytics platform to assess the safety profile of small molecules based on secondary drug targets. Dr. Racz has published multiple peer-reviewed articles describing safety database and ontology development, adverse event prediction, and pathway analysis. Dr. Racz holds a BS in Biomolecular Sciences and PharmD from the University of Michigan.

Presentation
Molecular Target Adverse-event Profile: Mechanistic Predictions for Drug Safety
Wednesday, April 3, 2019, 3:30 – 4:00 p.m.

Clinical trials are often not of sufficient size or duration to detect rare adverse events, and safety label changes often occur post-market. Predictive safety informatics can assist in identifying targets and events of concern. The Division of Applied Regulatory Science at FDA has developed a methodology to predict a wide range of significant adverse events using two machine learning algorithms, Naive Bayes and an ensemble classifier. These algorithms incorporate post-marketing data along with chemical features to identify adverse events based on known target profile. Further enhancements, including incorporation of predicted targets and identification of indication-related adverse event reports, are currently being incorporated.

Marjorie Rallins, Ph.D.
Chief Science Officer
Physicials Consortium for Performance Improvement
Chicago, IL

Marjorie Rallins, DPM, MSMI is Vice President and Chief Scientific Officer for the PCPI Foundation. She has oversight for the three focal programs of PCPI -Measurement Science, the NQRN® and Quality Improvement. Dr. Rallins is a strategic leader who consistently uses innovation strategies and leverages high performing teams to carry out the organizational mission and drive business results. She has more than ten years of experience in quality measurement and over twenty years of experience in health care informatics. Dr. Rallins has served on a number of HIT committees including co-chair of the Clinical Quality Workgroup of the Health Information Technology Standards Committee (HITSC), the CHIPRA Pediatric Quality Measure Program (PQMP) Workgroup and the Content Standards Workgroup, of the HITSC.

Presentation
Clinical Quality Measurement: Principles, Priorities and Opportunities
Thursday, April 4, 2019, 9:15 – 9:45 a.m.

Lynn Sanders, Ph.D.
Associate Chief Consultant for Pharmacy RE-engineering and Informatics
VHA Pharmacy Benefits Management
Washington, DC

Lynn Clark Sanders is the Associate Chief Consultant for the Veterans Affairs Pharmacy Benefits Management Clinical Informatics/Pharmacy Re-engineering Program, providing oversight of clinical informatics systems and an initiative to re-design, develop, and implement a VA national pharmacy informatics system. The VA has developed numerous pharmacy software and system improvements, including the largest government developed Clinical Decision Support system MOCHA, as well as the largest government managed drug file and formulary. Dr. Sanders is currently the lead Pharmacy Chair for VA's Electronic Health Record Modernization project to develop a shared system with the Department of Defense for a longitudinal health care record for active military and veterans.

Prior to this she served as the Director of Pharmacy for the Philadelphia Veterans Affairs Medical Center, which is a health care delivery system that services 50,000 patients. Among her professional and governmental responsibilities, she chaired the Regional (VISN) Pharmacy Utilization Management Committee that reviews and directed formulary and drug utilization for 10 hospitals in Pennsylvania, Delaware, and West Virginia.

Dr. Sanders was responsible for developing the first Medicaid Managed Care formulary approved by the state of Pennsylvania, during her 4 year tenure as director of a managed care corporation, AmeriChoice of Pennsylvania. Prior to taking a position in managed care, she was director of pharmacy for the 1000 bed Tampa General Hospital, where she was employed for 12 years, and developed many programs including a satellite pharmacy system.

Dr. Sanders achieved her bachelors' degree in Pharmacy from Howard University and went on to obtain her doctorate degree from Florida A&M University. Her managerial education includes certification programs from Duke University and Wharton School of Business, and is an alumnus of the National Leadership VA Training Program, and has a Masters Certificate in Project Management from George Washington University.

Dr. Sanders has had numerous speaking engagements focused on formulary management, controlling drug costs, healthcare information systems and various aspects of pharmacy practice. She has been a preceptor for pharmacy practice for Florida A&M University, and Philadelphia University of the Sciences.

Presentation
Data Standardization in the VA Pharmacy System, It's Applications and Benefits. Today and What's Next
Wednesday, April 3, 2019, 3:15 – 3:45 p.m.

The Department of Veterans Affairs Electronic Health Record – VistA was originally implemented in the 1990s but the system has continued to evolve and is one of the highest rated E HRs in the US. VistA is based on Open Source Code development that has been used as a platform for many E HRs in the world. The adoption of data standards in VistA including for its Computerized Patient Record System (CPRS), Pharmacy, and Bar Code Medication Administration (BCMA) has enabled VA to data share across its organization and with its health care partners using interoperability and data mapping. This presentation will discuss numerous impacts and benefits of data standardization that currently exist in the VA E HR and that are planned under VA's transformation to a longitudinal healthcare record with DoD using the Cerner system.

Shelly Spiro, Ph.D.
USP Affiliation: member of the USP HQ-Drug Allergy and Intolerance Classification Expert Panel
Executive Director
Pharmacy HIT Collaborative
Las Vegas, NV

Shelly Spiro is Executive Director of the Pharmacy HIT Collaborative (PHIT). PHIT is an organization of the major national pharmacy associations and associate members focused on advocating and educating key stakeholders regarding the use of health IT to better enable pharmacists to help optimize person-centered care by the inclusion of pharmacists within a technology-enabled integrated health care system. Spiro is active in national pharmacy associations, standards development organizations (NCPDP and HL7) and is a leader in Pharmacy health IT. She is an American Society of Consultant Pharmacists (ASCP) Past President and 2014 Archambault Award recipient. She earned her BSPharm degree in 1976 from University of Illinois College of Pharmacy She has authored several articles and is a national speaker on topics relating to various professional pharmacy, health IT systems, terminology, electronic prescribing, and pharmacist eCare plan.

Presentation
Applied Clinical Informatics: Drug Allergies and Intolerances
Wednesday, April 3, 2019, 10:00 – 10:30 a.m.

Adverse Drug Reactions (ADRs) and drug allergies is a public health concern. Standardizing and codifying electronic drug allergies and intolerances documentation within electronic health records (EHRs) has been worked on by the standards development organizations and USP. This session will discuss these efforts and identify the progress of the USP Allergies and Intolerance Expert Panel.

Brad Tice, Pharm.D., MBA, FAPhA
President-Elect
APhA
Washington, DC

Brad Tice, PharmD, MBA, FAPhA is the current President of the American Pharmacists Association. He currently serves as SVP of Pharmacy Practice at Aspen RxHealth and CEO of RxGenomix. Dr. Tice received his bachelor of science from the University of Kansas in 1994 and PharmD in 1996. He also received an MBA from Vanderbilt University Owen School of Management in 2012. His career has spanned pharmacy wholesaler, entrepreneurial start-up, chain pharmacy, academia, and managed care. He has focused his entire career on developing, implementing and advocating for pharmacists' services to enhance the ability to improve patient care and for pharmacists to be recognized and compensated for that value. He has served the profession in numerous capacities including the Pharmacy Quality Alliance, serving as initial consultant to help get quality measurement on pharmacy started and on technical expert panels on quality measure development (NCQA, CMS) and improving MTM within Medicare Part D (CMMI). He has also served the American Pharmacists Association as speaker of the APhA House of Delegates and currently serves on the board of trustees as member-at-large. He has served in numerous elected positions within the Academy of Pharmacy Practice and Management (APPM) and was a national member-at-large as a student pharmacist. His professional recognitions include being named Product Leader of the Year in 2015 for Cardinal Health, Distinguished Achievement Award in Clinical/Pharmacotherapeutic Practice, 2010, American Pharmacists Association—Fellow, 2008, Albert B. Prescott /GlaxoSmithKline Leadership Award 2005, and Iowa Pharmacy Association, Young Pharmacist of the Year in 2002.

Presentation
Applied Clinical Informatics: Drug Allergies and Intolerances
Wednesday, April 3, 2019, 11:45 – 12:15 p.m.

Joseph Tonning, Ph.D.
FDA
Washington, DC

Dr. Tonning is the Associate Director for Biomedical Informatics in the Office of New Drugs, Division of Bone, Reproductive, and Urologic Products, in the FDA's Center for Drug Evaluation and Research. During his time at the FDA, he has spearheaded various data mining initiatives and served as the FDA liaison for the FDA-PhRMA Safety Evaluation Tools Working Group. Subsequently, he served as a Co-Chair of the New Molecular Entity Steering Committee which developed a system for tracking the safety of new drugs recently approved by the FDA. This program became part of the FDA's strategy for implementing Section 915 of the Food and Drug Administration Amendments Act (FDAAA). He currently serves as Co-Chair of the FDA Data Mining Council and as Coordinator of the Center's Biomedical Informatics Working Group. His research interests also include natural language processing and he served as the project lead representative for the FDA on the FDA-NLM Labeling Project, a natural language processing research partnership between the FDA and the National Library of Medicine.

Dr. Tonning is a registered pharmacist and completed a bachelor's degree in pharmacy from the University of Georgia. After his pharmacy training, he completed a residency in hospital pharmacy at the Medical College of Georgia. He then earned a Doctor of Medicine Degree at the Medical College of Georgia and completed both a residency in preventive medicine and a clinical fellowship in occupational medicine at Johns Hopkins where he also attained a Master of Public Health Degree. Upon completing his residency at Johns Hopkins, Dr. Tonning received a commission as an officer in the United States Public Health Service, practicing medicine in clinics operated by the U.S. Coast Guard, U.S. Navy, and U.S. Capitol. During this time, he conducted data and policy research on injuries and fatalities in motor vehicle crashes for the U.S. Department of Transportation, coordinating reports to Congress and the President. He is board certified in both clinical informatics and occupational medicine.

Presentation
Clinical Informatics at the FDA
Thursday, April 4, 2019, 4:00 – 4:30 p.m.

This presentation will summarize some of the clinical informatics initiatives at the U.S. Food and Drug Administration, mainly within the Center for Drug Evaluation and Research. Examples of some of these initiatives include disproportionality analysis ("data mining"), natural language processing ("text mining"), and geographical information systems. Databases and software tool approaches that the FDA uses to identify potential safety signals will also be discussed. At the FDA, disproportionality analyses are used to identify statistical associations between products and events within large databases containing safety reports. Such analyses compare the observed count for a product-event combination with an "expected" count. Unexpectedly high reporting associations may indicate a "signal" of a possible causal association between a specific adverse event and product of interest. Natural language processing is used by the FDA because of the large volume of data submitted in "unstructured" formats, such as clinical narratives and descriptions of adverse events. Geographical information systems (GIS) are used in decision making by providing geographic displays of potential safety issues by city, state, or region. GIS can incorporate temporal data to create spatio-temporal (space-time) graphical displays for analysis. Geographical displays of potential safety issues can help to identify populations at risk to identify areas where public health education and assistance may be needed. These and other clinical informatics initiatives at the FDA are important to improve efficiency, reproducibility, and more accurate interpretation of data.

Dana Vanderwall
Bristol-Meyers Squibb
Boston, MA

Dana Vanderwall has over twenty years of experience in the pharmaceutical industry as a scientist and IT professional, and is currently Head IT Business Partner for Biology & Pre-Clinical Research at Bristol-Myers Squibb. In his current role he is accountable for the strategy and planning to enable data flow, analytics, knowledge capture, and provide general laboratory informatics capabilities to the Biology, Pharmaceutical Candidate Optimization, Drug Safety Evaluation and Veterinary Sciences functions at BMS. He is also currently Chair of the Allotrope Foundation Board of the Directors, and as a co-founder helped develop the concepts and strategy that led to the launch of Allotrope in 2012. He also contributes to projects within the Pistoia Alliance and is active in the Society for Lab Automation and Screening, most recently as Co-chair of the 2017 SLAS Conference. Prior to joining BMS Dana was at GlaxoSmthKline and Merck, and has traversed Computational Chemistry, Cheminformatics, Computational & Structural Biology, Biochemistry and R&D IT. He received his B.S. in Biochemistry at the University of Wisconsin, and Ph.D. in Biochemistry at University of Maryland.

Presentation
Standardizing Data and It's Context from Planning Through Capture to Facilitate Consumption and Analysis
Thursday, April 4, 2019, 1:00 – 1:20 p.m.

The way people create and manage analytical data has evolved from simple measurement capture to a wide variety of secondary uses. These combine the measurements, meta data about the measurements and even data from what might have been thought of as unrelated areas to derive answers for questions about unexpected results, business process optimizations and business insights that by themselves are not obvious by simply looking at the empirical measurements. With this has risen the need for vendor neutral data to support inter-operation between data systems and support for large data lakes of information. Waters will explain its approach to vendor neutral data and our support of the Allotrope Foundation.

Allotrope Foundation is an international consortium of pharmaceutical and biopharmaceutical companies created to revolutionize the way we acquire, share and gain insights from scientific data, through a community and the framework for standardization. The Foundation draws from the breadth and diversity of expertise of subject matter experts across over 60 member companies, vendors and academic institutions. Through a strong collaborative culture, the Allotrope Community has partnered to deliver a "real world" solution to address the root cause of common challenges in the scientific data landscape. This initiative has led to breakthroughs that enhance data integrity, reduce manual effort, enable seamless interoperability, and drive the realization of the full value of scientific data.

The Allotrope Framework implements a single, universal data format (Allotrope Data Format, ADF) and addresses data quality at the source through ontologies and data models that provide the standard language for describing the equipment, processes, materials, and results covering a broad range of techniques and instruments. The ADF is now established as the most easily extensible instrument, technique, vendor and platform agnostic standard format for data. In addition, it is the first format that integrates semantic standards and capabilities with the data storage, enabling an unprecedented connectivity in the bio-pharmaceutical domain.

Following an overview of Allotrope Foundation and the Framework, this will feature examples that demonstrate how the Allotrope Framework is being implemented in solutions developed by

Allotrope Partners, which are the cornerstone of adoption across the industry and are powering our digital transformation. TetraScience joined Allotrope Partner Network in 2017 and since then has been one of the most active partners and contributors to Allotrope framework. TetraScience is a Data Integration and Insights Platform for the Life Sciences. With TetraScience, laboratories connect critical information sources from instruments and lab systems to a cloud-based data platform. Data is centralized and standardized and available to downstream targets resulting in improved data management and streamlined process.

TetraScience is currently leveraging its Data Integration Platform to collect, standardize and centralize the siloed data sets from scientific instruments, CRO/CMO, software databases. Based on this platform, TetraScience is actively working with Allotrope and Waters together to create the first Allotrope Data Format converter for Waters Empower data. This community project will lead to the various uses cases around semantic search, seamless interoperability, data analytics, and many others.

Siping Wang, Ph.D.
Tetrascience
Boston, MA

Siping Wang. Co-founder and CEO of TetraScience, a Boston based cloud technology company that provides Data Integration Platform for Life Science R&D. Cornell Engineering Physics and MIT EECS. Forbes 30 Under 30 in Science.

Presentation
Standardizing Data and It's Context from Planning Through Capture to Facilitate Consumption and Analysis
Thursday, April 4, 2019, 1:20 – 1:40 p.m.

The way people create and manage analytical data has evolved from simple measurement capture to a wide variety of secondary uses. These combine the measurements, meta data about the measurements and even data from what might have been thought of as unrelated areas to derive answers for questions about unexpected results, business process optimizations and business insights that by themselves are not obvious by simply looking at the empirical measurements. With this has risen the need for vendor neutral data to support inter-operation between data systems and support for large data lakes of information. Waters will explain its approach to vendor neutral data and our support of the Allotrope Foundation.

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Jon White, Ph.D.
Deputy National Coordinator
Office of the National Coordinator of Health IT
Washington, DC

Dr. Jon White serves as deputy national coordinator for health information technology. The family physician has dedicated his career to improving health and health care quality through the use and sharing of electronic health information. At ONC, Dr. White provides high level executive direction and leadership for all ONC programs and policies, and advances key priorities. He has led mission-critical activities, including the publication of high priority, nationally impactful regulations, the publication of the Shared Nationwide Interoperability Roadmap, a widely-publicized congressional report on information blocking, and ONC's efforts in the precision medicine initiative.

Before his service at ONC, Dr. White was director of the division of health IT at the Agency for Healthcare Research and Quality (AHRQ). In his role at AHRQ, he directed hundreds of projects in 48 states, including research, demonstration and implementation projects on a wide variety of health IT applications and issues. Dr. White has deep experience working with federal government partners (including the Centers for Medicare & Medicaid Services and the Department of Veterans Affairs), as well as key health care professional, patient, policy, and health IT stakeholder groups to implement major health care initiatives.

Dr. White trained in family medicine at the University of Virginia and Lancaster General Hospital in Pennsylvania. He is a recipient of the national AAFP Award for Excellence in Graduate Education.

Presentation
21st Century Act Cures Implementation
Wednesday, April 3, 2019, 1:30 – 2:00 p.m.