PRISME Forum

Pharmaceutical R & D Information Systems Management Executives

PRISME Forum

TECHNICAL MEETING

New Ways of Generating Insights in Biopharmaceutical R&D

PRISME Forum Chair:

Olivier Gien, *Sanofi*

PRISME Forum Technical Meeting Chair:

Martin Leach, *Alexion Pharmaceuticals*

November 16 - 17, 2016

San Diego, California - USA

Host: Celgene

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PRISME Forum Fall 2016 Technical Meeting App:

http://my.yapp.us/PRISMETECH

Meeting Venue

All sessions will be hosted by Celgene and held at Green Acre Campus Pointe, 10300 Campus Point Drive, San Diego, CA 92121 USA.

Hotel

Hyatt Regency La Jolla at Aventine, 3777 La Jolla Village Dr, San Diego, CA 92122 – USA.

Contacts

Program Coordinator:		+44.77.68.173.518/jcmwise@prismeforum.org
Secretariat	Office:	+1.224.938.9523/logistics@prismeforum.org
	On site, SMS:	+1.312.622.1234

PRISME Forum Technical Meeting Advisory Committee

Olivier Gien
Chair, PRISME Forum
Global Head, Clinical IT, *Sanofi*

David Christie
VP, R&D Informatics, *Amgen*

Joel Ekstrom
VP, Informatics, *Ionis Pharmaceuticals*

Martin Leach
Chair, PRISME Forum Technical Meeting
VP, R&D IT, *Alexion Pharmaceuticals*

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Technology Innovation Director, *AstraZeneca*

Ashok Upadhyay
Senior Director, Global R&D IT, *Otsuka Pharmaceutical Development & Commercialization*

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PRISME Forum Host

The PRISME Forum Technical Meeting Advisory Committee would like to thank Celgene for hosting the 2016 PRISME Forum Fall meeting.

PRISME Forum Statement of Compliance

"All meetings, working groups and communications will be open to all Members and any records thereof will be non-confidential and available for inspection by any Member. The Members acknowledge that discussing any commercially sensitive topics, including costs, volumes, inventories, sales level methods, channels of distribution, access to future products, markets, current or future prices, profitability, ***contract pricing or trading terms*** is prohibited. The Members of PRISME will strictly comply with all laws relevant to their activities, including US state and federal anti-trust laws and European competition laws."

THEME

New Ways of Generating Insights in Biopharmaceutical R&D

BACKGROUND

R&D is at the center of innovation in the biopharmaceutical industry. It is both a challenge to – and an opportunity for - leaders in biopharmaceutical R&D IT to understand, encourage and enable this innovation and to bring new methodologies, approaches, capabilities and technologies to support this ever-evolving landscape of R&D strategies. As such, leaders in R&D IT must stay abreast of emerging trends and technologies. Furthermore, it is not uncommon for R&D IT to perform R&D in IT to create new capabilities that once recognized and acknowledged by other IT groups in other functions in biopharma get leveraged further across the enterprise.

At the PRISME Forum Spring 2016 meeting, key industry trends were identified in Cloud, Digital & Mobile Health Technologies, Big Data, and Knowledge Management. The PRISME Forum Fall 2016 meeting will be held in California, close to the hotbed of innovation in Silicon Valley. As such, the PRISME Forum is keen to bring insights into these areas of interest as well as exploring some of the collaboration/social technology areas that are prevalent in this location.

Through an engaging agenda with established and emerging companies and technologies, the meeting will - using a variety of approaches - explore new methods of R&D enablement. Likely topics will include data exploration, knowledge creation, health monitoring and management and intelligent collaboration. Leveraging the expertise of venture capitalists, delegates to this Technical Meeting will gain wider insights into additional emerging trends that could be applied to biopharmaceutical R&D to enable insight generation.

FOCUS

The agenda for this PRISME Forum Fall 2016 Technical Meeting will focus on relevant topics including:

- New technologies enabling new ways of managing clinical trials
- Emerging trends in R&D/Healthcare IT investment
- Digital health approaches and technologies including mobile
- Data aggregation, distillation and visualization – including 'omics' and Real World Evidence
- Knowledge management approaches including computational linguistics and
- Application portfolio simplification
- Collaboration technologies

PROGRAM

All sessions will be held at Green Acre Campus Pointe (10300 Campus Point Drive San Diego, CA 92121).

WEDNESDAY, November 16, 2016		
18:15	*Gather in hotel lobby for departure to PRISME Forum Group Reception (Business Meeting delegates and Technical Meeting delegates) Bali Hai at 2230 Shelter Island Dr, San Diego, CA 92106*	
THURSDAY, November 17, 2016		
08:00	*Gather in the hotel lobby for departure to the meeting venue*	
08:30	*Check-in; poster installation*	
08:45	**Welcome Notes**	**Olivier Gien,** Chair, *PRISME Forum;* Global Head, Clinical IT, *Sanofi*
08:50	**Introductions**	**Martin Leach,** Technical Meeting Chair, *PRISME Forum;* VP, R&D IT, *Alexion Pharmaceuticals*
SESSION I: Keynote Presentations		**Chair: Martin Leach,** VP, R&D IT, *Alexion Pharmaceuticals*
09:00	**Trends in Life Science & Healthcare R&D IT**	**Peter Gassner**, Founder & CEO, *Veeva Systems*
09:45	**Internet of Medical Things: Smart, Patient-Centered and Frictionless**	**Gene Dantsker,** Director, Business Development, *Qualcomm Life*
10:30	*Coffee Break*	
SESSION II: Perspectives: *Picking and Backing the Next Horse in R&D IT*		**Chair: Martin Leach,** VP, R&D IT, *Alexion Pharmaceuticals*
11:00	**The Entrepreneur's Perspective**	**Noah Craft,** CEO, *Science 37*
11:10	**The Biopharma Strategic Fund R&D / Healthcare Perspective**	**Abhishek Shankar**, Vice President, Industry Head Life Sciences, *HCL America*
11:20	**The Biopharma R&D IT Perspective / Innovation**	**George Goldsmith,** Sr. Director, Business & Technology Transformation, *Otsuka*
11:30	**Technology Venture Fund Perspective – Technology Investments**	**Jim Doehrman**, Operating Partner, *Sierra Ventures*
11:40	**The Biopharma R&D IT Perspective / Innovation**	**Hal Stern,** Executive Director, Applied Technology, *Merck*
11:50	***Moderated Panel Discussion – Q&A***	
SESSION III A: Posters		**Chair: Joel Ekstrom,** VP, Informatics, *Ionis Pharmaceuticals*
12:30	*Introduction - Poster Rotations (three 15 minute rotations)*	
P1	**Proactive Medication Safety Surveillance**	**Richard Loomis,** CMO and VP, Informatics, *Practice Fusion* **J. Michael Sprafka,** Executive Director, Center for Observational Research, *Amgen*
P2	**Big Data Processing & Analytics**	**Bavesh Patel,** Vice President, Sales Go-To-Market, *Databricks*
P3	**The Tumor Model Compendium: Knowledge Sharing for Immuno-Oncology Hypothesis Testing**	**Sabine Schefzick,** Director, Oncology & Vaccine R&D BT, *Pfizer* **Peter Roberts,** Manager, Oncology & Vaccine R&D BT, *Pfizer*
P4	**Kratos: Enabling Single Cell Genomics**	**Rajiv Pande,** President and CEO, *Smpl Bio*
P5	**Augmenting the Reality of Healthcare**	**Robert Zambon,** Chief Scientist, *Booz Allen Hamilton* **Nirav Desai,** Chief Technologist, *Booz Allen Hamilton*
P6	**Deep Learning Technology in Healthcare**	**Lina Nilsson,** COO, *Enlitic Inc.*
13:15	*Lunch*	
SESSION III B: Posters		**Chair: Joel Ekstrom,** VP, Informatics, *Ionis Pharmaceuticals*
14:15	*Poster Session (Remaining three 15 minute rotations)*	
SESSION IV: Plenary Presentations		**Chair: Kim Smyth,** Technology Innovation Director, *AstraZeneca*
15:00	**Real World Evidence Generation: Preparing for the Future**	**Cathy Critchlow,** VP, Center for Observational Research, *Amgen*
15:30	**Changing the Shape of Preclinical Research and Clinical Practice Through 3D Bioprinted Organs**	**Eric David,** Co-founder & Chief Strategy Officer, *Organovo*
SESSION V: Meeting Summary & Awards		**Chair: Martin Leach,** VP, R&D IT, *Alexion Pharmaceuticals*
16:00	**Meeting Summary**	
16:30	*Awards*	
16:45	***Networking Reception***	
18:00	*Return to the hotel*	
18:45	*Gather in hotel lobby for departure to informal dinner*	

BIOS AND ABSTRACTS

PRISME Forum Chair: Olivier Gien

Global Head, Clinical IT, *Sanofi*

Olivier Gien, PhD, was elected as the Chairman of the PRISME Forum at the November 2014 PRISME Forum Business Meeting.

Dr. Gien is the Global Head of Clinical IT at Sanofi. He is a Chemical Engineer by training and holds a PhD in Organic Chemistry. His PhD work focused on leveraging Artificial Intelligence technologies and retrosynthetic analysis to build a system helping chemists in the design of synthetic routes.

Dr. Gien started his career in the Exploratory Unit of Sanofi's Hungarian affiliate in Budapest then took charge of Information Systems for Industrial Chemical development at Sanofi's Sisteron site. He led then Global Discovery Research Information Systems at Sanofi-Synthelabo, then Sanofi-Aventis in Montpellier, before taking on his new role in Paris area in 2010.

PRISME Forum Technical Meeting Chair: Martin Leach

VP, R&D IT, *Alexion Pharmaceuticals*

Martin Leach, PhD, is Vice President IT for R&D at Alexion Pharmaceuticals. Prior to Alexion, he led the R&D IT group and created the first Data Sciences group then subsequently led the Global Data Office at Biogen.

Prior to Biogen, Dr. Leach was the CIO of the Broad Institute of MIT & Harvard. He also led a team of several hundred IT professionals and contractors at Merck & Co before his time at the Broad Institute. Here he provided information technology and research computing to Discovery & Pre-clinical Sciences at Merck Research Laboratories.

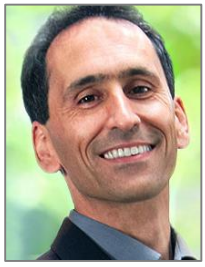
Dr. Leach has worked with several other pharmaceutical, biotechnology and life sciences organizations as part of Booz Allen Hamilton, where for 2 years, he was a leader in their IT strategy practice. Prior to Booz Allen, he had the CIO role, leading the IT and Informatics at CuraGen Corporation and worked with 454 Corporation to create their bioinformatics function.

He obtained his PhD in pharmacology from Boston University School of Medicine. He is a member of Silicon Valley advisory groups on technology for Sierra Ventures and Canaan Partners. Recent awards include 2011 CIO Magazine award for “Ones to Watch” and in 2012 he was voted FierceBiotech’s Top 10 Biotech Techies.

SESSION I
KEYNOTE PRESENTATIONS

Session Chair: Martin Leach
VP, R&D IT, *Alexion Pharmaceuticals*

Peter Gassner
Founder & CEO, *Veeva Systems*



Peter Gassner is responsible for the overall direction and management of Veeva Systems. In 2010, Peter was named to the PharmaVOICE 100, which recognizes the 100 most influential people in the life sciences industry. Peter is a twenty-year veteran of the software industry.

Prior to founding Veeva, Mr. Gassner was senior vice president of technology at salesforce.com, where he had responsibility for building the salesforce.com platform including product, marketing, and developer relations. During his tenure, salesforce.com completed its public offering and grew the technology into the most successful SaaS platform in the industry.

Before salesforce.com, Mr. Gassner was with PeopleSoft for nine years as both Chief Architect and General Manager of PeopleTools. He led a team of over 450 professionals who provided the development, strategy, marketing and customer support for PeopleSoft's technology platform. PeopleTools was widely regarded in the industry as the best application platform of its day.

Mr. Gassner began his career with IBM in relational database development and research at IBM Silicon Valley Lab and then at IBM Almaden Research Center, where he had the privilege of working closely with some of the inventors of relational database technology.

He serves on the board of directors of Veeva Systems, Guidewire Software, and Zoom Video Communications.

Mr. Gassner holds a Bachelor of Science in Computer Science from Oregon State University.

Trends in Life Science & Healthcare R&D IT

Gene Dantsker

Director, Business Development, *Qualcomm Life*

Gene Dantsker, PhD, is Director of Business Development at Qualcomm Life.

Prior to this role, Dr. Dantsker worked across the spectrum of sensor, therapy and diagnostic technology solutions with broad experience in semiconductor, medical and biotech businesses.

Dr. Dantsker was Senior Technical Staff Member at TRW, Inc., Space and Electronics Division where he was responsible for design, fabrication, and integration of microelectronics for space/satellite applications. Subsequently he co-founded Nanostream, Inc., a biotech company and provider of high-throughput bio-analytical instruments to companies involved in drug discovery and development.

As VP of Technology, Dr. Dantsker was co-inventor and developer of Nanostream's core technologies based on polymer MEMS microfluidics and converted them into commercial products purchased by leading pharmaceutical companies. He then served as CEO and CTO of Adnavance Technologies, Inc., a provider of ultra-sensitive medical diagnostic products, operating out of the US and Canada.

Dr. Danstker also served on the Board of Directors of D-Wave Systems, a pioneer in Quantum Computing, with leading Silicon Valley VCs, as well as heavily consulted the company in business development, general and IP strategy, growth strategy and operational infrastructure. He subsequently provided business development support for the US branch of Nitto Denko, a leading supplier of diversified polymer-film products based in Osaka, Japan.

Dr. Dantsker holds BS degrees in Physics and Mathematics from the University of Maryland, MA and PhD in Physics from the University of California at Berkeley, and an MBA from San Diego State University. He is an inventor on over 25 patents.

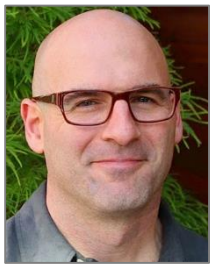
Internet of Medical Things: Smart, Patient-Centered and Frictionless

Modern health care is undergoing an unprecedented shift from volume-driven to value-driven medicine, characterized by outcome-based payment models and enabled by disruptive technologies that are decentralizing health care and engaging the patient at all stages of pharmaceutical development, spanning clinical trials through post-market. As more and more medical devices generate a wide variety of data, a growing Internet of Medical Things (IOMT) is enabling new care delivery models that are safe, secure, and intelligent. We will address factors that are driving the shift toward connected, patient-centered health and how mobile connected solutions are transforming health care.

SESSION II
PERSPECTIVES: *Picking and Backing the Next Horse in R&D IT*

Session Chair: Martin Leach
VP, R&D IT, *Alexion Pharmaceuticals*

Noah Craft
CEO, *Science 37*



Noah Craft MD, PhD, is the co-founder and CEO of Science 37 and a physician-scientist-entrepreneur.

Science 37 transforms the clinical research process, accelerating biomedical discovery and reducing clinical trial costs by shifting the center for research from traditional institutional investigative sites to the patient's home and local healthcare system. We use our patient-centered technology platform (NORA®) to create metasites™, simplify the process of participating in trials, and connect patients safely and securely to the world's best scientists, no matter where they live.

For 10+ years, Dr. Craft has worked on the skin microbiome, parasite immunology, and cancer vaccine development. He also serves as a senior strategic advisor to both VisualDx and Direct Derm. He has published more than 45 peer-reviewed research manuscripts and holds multiple patents.

Dr. Craft received a BS from Brown University, completed medical school, residency, and post-doctoral research at UCLA.

The Entrepreneur's Perspective

Abhishek Shankar

Vice President, Industry Head Life Sciences, *HCL America*

Abhishek Shankar is responsible for HCL America's Life Sciences Industry group, which includes Biopharmaceutical, Medical Devices and Adjacency industries. As a part of this function, he is tasked with creating higher mind share leading to market share. This role involves leading a business which keeps HCL at the helm of digital transformation led industry solutions which impact axes of revenue, business cycle time and profitability of client organizations, while maintaining highest level of compliance. Specifically impacting through digitization towards creating an integrated "as a Service" platforms that helps bring product to market and expanding human lives is an area of seamless interest and expertise.

Mr. Shankar began his career at HCL writing software code in Developer 2K way back in '99. After a sabbatical at B School he enrolled into HCL's SMT (Senior Management Trainee) program which would put him into multiple role rotations in years to come. His first assignment as an Exec Assistant to HCL C Suite included stints across operations management, corporate planning, and marketing. This led to an opportunity to incubate HCL's Life Sciences business in 2004, wherein he moved to the US as a part of an internal Start Up initiative.

In a further role rotation, Mr. Shankar took a corporate position to lead HCL's Digital, Brand Marketing and thought leadership functions. Here, he led efforts in brand positioning activities that reach out to target audiences through multi-channel marketing campaigns powered by Digital Transformation of Marketing functions. He headed HCL's industry leading "Digital and Social Media" as a part of Brand Marketing. He was also responsible for HCL representation at the World Economic Forum at Davos.

As an IT industry thought leader, he consults extensively on brand positioning, digital strategies, intrapreneurship and tries to stay relevant in an ever changing world. Mr. Shankar has delivered case studies and lectures at leading institutions including, Harvard Business School, Stern School of Business, Imperial College of London, IIM Lucknow amongst others on subjects ranging from Brand to human technology.

The Biopharma Strategic Fund R&D / Healthcare Perspective

As they look for further innovation inputs, Pharma firms increasingly turn to external sources, both fund based and non-traditional avenues to foster innovation.

Leveraging operating expertise, cost discipline, in-house R&D capability, cutting-edge technology adoption and access to proprietary capital to fuel growth, large service partners such as HCL are in a unique position to nurture radical transformation in the Pharma value chain. Using the context of investments made by HCL Innovation Fund in three pivotal areas of value creation - Innovation harvesting within IT, Persona or user based innovation and sunset IT innovation, this session explores how value can be created in the ecosystem using non-traditional sources and what the future beholds.

George Goldsmith

Sr. Director, Business & Technology Transformation, *Otsuka Pharmaceutical Development & Commercialization*

George Goldsmith has over 20 years of experience as an IT Leader in the Pharmaceutical Industry. He has a MS in Information Systems and is certified in the Governance of Enterprise IT, CGEIT.

He has successfully managed the delivery and support of IT Systems & Services for the following pharmaceutical companies: GlaxoSmithKline, Bristol-Myers Squibb, Allergan (Forest Laboratories), and currently Otsuka.
He has managed the delivery of numerous systems across the pharmaceutical value chain from Discovery, Exploratory Development, Clinical, Regulatory, Manufacturing and Commercial.

Mr. Goldsmith has partnered with Researchers and Clinicians with the delivery of novel systems and processes for Automated Compound Storage and Retrieval, QTc Interval Prolongation Viewers, Direct Data Capture at the Central Pharmacology Unit, and Clinical Genetic Sample Banking while at B-MS.

He has successfully managed IT Portfolios and Budgets in excess of $160M, and has also established highly valued Vendor Management and Integration Management Offices through multiple Mergers and Acquisitions, and he has also partnered with Corporate Officers in the development of corporate compliance programs for Information Management while at Allergan (Forest Laboratories).

Mr. Goldsmith currently leads Business and Technology Transformation at Otsuka with a focus on the adoption and use of digital technologies such as wearable or IoT devices, patient monitoring and reported outcomes, centralized control and monitoring of clinical trials and integration of real-world data within clinical development.

The Biopharma R&D IT Perspective / Innovation

Jim Doehrman

Operating Partner, *Sierra Ventures*

Jim Doehrman has worked with members of the Sierra team in various capacities for over 15 years and formally joined the team last year as its first Operating Partner.

Prior to joining Sierra, Mr. Doehrman had COO, CAO and CFO roles at public and private technology companies and most recently, led explosive growth at two venture capital backed private software companies (digital media pioneer Gracenote -- sold to Sony, and Automotive SaaS company Xtime, -- sold to Cox Communications (AutoTrader group).

Mr. Doehrman had his operational and finance training in the public accounting, retail and media industries, including International assignments in London and Mexico City and led the initial IPO of the publisher of The Dummies" books (eg "DOS For Dummies"). During his career, he has led scores of M&A, debt and equity financing deals valued cumulatively at over $4Bn.

Technology Venture Fund Perspective – Technology Investments

Sierra Ventures is an early-stage technology venture capital firm based in Silicon Valley. Since 1982, investors have trusted us with almost $2 billion in capital to help hundreds of entrepreneurs around the world begin and grow successful technology companies. Our passion is finding the right combination of innovative technology and talented entrepreneurs, and guiding them with expertise and capital to help companies grow and deliver on their promise. We invest globally and have historically focused on B2B IT technology investments, including Big Data, Cloud, Devices, Mobile, IT infrastructure and SaaS. We also invest in emerging technologies, which today includes Consumer Marketplaces, Machine learning/AI, Next-generation communications, Robotics, and Virtual/Augmented Reality.

Jim Doehrman will explain how Sierra Ventures seeks to find and invest in target opportunities in a very competitive VC/technology start-up landscape and how they nurture their investments towards their defined exit strategy. He will introduce to the discussion some of the metrics deployed, and the engagement opportunities sought, to interface nascent technology companies with their anticipated customer base.

Hal Stern

Executive Director, Applied Technology, *Merck*

Hal Stern is Executive Director of Applied Technology at Merck, where his group builds disruptive services and architectures for healthcare technology, data ingest, privacy, consent and improved precision computing. Current interests include the use of blockchain to improve consent and federation of health care data, applications of graph algorithms to very large domains, and applying machine learning to privacy constraints.

Prior to Merck, Mr. Stern was a VP at Juniper Networks and spent more than 20 years at Sun Microsystems in a variety of technical leadership roles. He earned a BSE degree in Electrical Engineering and Computer Science from Princeton University and holds eight patents in the areas of security, identity, user experience, and networking.

Mr. Stern has been a frequent speaker at industry and technical conferences, and has co-authored three books. He serves on the Princeton University CIO Advisory Council, the board of the Microfinance Information Exchange, and the Graduate Board of the Colonial Club of Princeton University.

The Biopharma R&D IT Perspective / Innovation

Science fiction and popular culture have created a view of science that feels like Disney's "Carousel of Progress" — there's a great big beautiful tomorrow there and everything will be happy and hopeful. Our experience with technology, whether in R&D or in delivery, is frequently the opposite in healthcare.

How do we apply design thinking to this problem and create opportunities for disruption?

1. Looking at industry standards and disruptive technologies: What axis of disruptive is most vital? Cost? Time? Scale? Market creation?

2. How do you use these new entrants to create an architecture for participation, so you aren't shouldering the entire burden or ecosystem?

3. What are the policy implications, from privacy to security to operational scale?

4. How do you accomplish the above where you need to play in a 2-sided market, or create the 2-sided market, and need to work out intellectual property, copyright, derivative rights, and shared development?

SESSION III
POSTERS

Session Chair: Joel Ekstrom

VP, Informatics, *Ionis Pharmaceuticals*

Joel Ekstrom has been working in the Life Science IT area for over 25 years, with a strong focus on R&D systems. He currently is CIO/Vice President, Informatics for Ionis Pharmaceuticals (formerly known as Isis Pharmaceuticals), based in Carlsbad California. Mr. Ekstrom is responsible for all aspects of Information Technology at Ionis, a company particularly focused in R&D. Prior to joining Ionis in 2015, Joel was the VP and Global Head of R&D Informatics at Daiichi Sankyo, Inc., responsible for IT strategy and operations for the Global R&D function. Prior to joining Daiichi Sankyo, Joel was the Global Head of Process Excellence and Performance Management at Hoffmann-La Roche based in Basel, Switzerland - responsible for implementing the Global Informatics Operating Model which included Project Management, Validation, and other services with the Informatics Function of Roche.

Mr. Ekstrom has held a number of other IT leadership roles in Pharmaceutical and Biotech organizations including Elan Pharmaceuticals, Baxter Healthcare, Schering AG, and Santen Inc. - delivering strategy, operations, globalized systems/processes, and organizational change management for Global R&D Business Functions or local subsidiaries. He holds degrees in Computer Science and Business Administration that provide both the technical foundation as well as the business acumen for aligning strategy to technology investments.

Richard Loomis

Chief Medical Officer and VP, Informatics, *Practice Fusion*

Richard Loomis, MD, leads the health informatics and research teams at Practice Fusion.

He is a strong advocate for advancing health IT and is the current Vice Chair of the HIMSS Electronic Health Record Association (EHRA).

Dr. Loomis completed his fellowship in biomedical informatics at Harvard and received his MD from the University of Michigan.

J. Michael Sprafka

Executive Director, Center for Observational Research, *Amgen*

J. Michael Sprafka is an epidemiologist with expertise in pharmacovigilance, outcomes research and pharmacoeconomices. He has twenty-five years' experience in leadership roles of pharmacovigilance, epidemiology and pharmacoeconomic functions. Product categories include anti-infective, musculoskeletal, gastrointestinal, cardiovascular, inflammation, and women's health.

Dr. Sprafka is the head of the Bone/Inflammation/Nephrology Therapeutic Area, Center for Observational Research at Amgen. He is responsible for the design and conduct of epidemiologic research and chair of the Observational Research Review Group responsible for the technical oversight and review of all observational research conducted at Amgen.

Prior to joining Amgen, he was VP of Consulting for Kendle, a Clinical Research Organization, responsible for regulatory submissions and outcomes research for pharmaceutical clients. From 1994 to 2009 Dr. Sprafka was a Senior Director of Pharmacovigilance, Epidemiology & Pharmacoeconomics for Procter & Gamble Pharmaceuticals responsible for the safety evaluations of both clinical and post-marketed products as well as the design and conduct of epidemiologic and economic research. From 1986 to 1994 he was an Associate Professor of Epidemiology at the University of Minnesota, School of Public Health and conducted research in the areas of cardiovascular disease, diabetes and cancer. From 1981 to 1985 he was a staff epidemiologist at the Minnesota Department of Health supporting the Diabetes Prevention Program sponsored by the CDC.

P1: Proactive Medication Safety Surveillance

Amgen was required by the FDA under Section 505(o) of the Federal Food, Drug, and Cosmetic Act (FDCA), to conduct postmarketing studies as indicated in the approval letter for Prolia, an injectable drug to treat osteoporosis. The requirement included a long-term surveillance study in patients administered Prolia to prospectively evaluate selected Adverse Events of Special Interest (AESI). After five years of a ten-year study, voluntary health care provider (HCP) registration and adverse event reporting was insufficient to address program objectives. To improve reporting, Amgen and Practice Fusion proposed an enhanced Prolia Postmarketing Active Safety Surveillance Program (PASP) using leading electronic health record (EHR) technology to access providers at the point-of-care and subsequently available de-identified patient data.

Bavesh Patel

Vice President, Sales Go-To-Market, *Databricks*

Bavesh Patel has 20 years of experience working within the Enterprise Technology space. He currently serves as Vice President of Sales Go To Market at Databricks. Databricks was founded by the creators of Apache Spark, and Bavesh's primary focus is to help companies connect the lines between Databricks & Spark capabilities to industry use cases that derive business value.

Mr. Patel has worked within the Health and Life Sciences space for over a decade. Prior to Databricks he lead Global Marketing for Edifecs, a software technology that integrated providers and payors. Before that he worked at Axway, a global technology company, and developed integration solutions for Pharmaceutical and Biotechnology companies.

P2: Big Data Processing & Analytics

Databricks has developed a Cloud Platform for Enterprises to leverage Apache Spark in secure, scalable and collaborative environment. Apache Spark is being leveraged in a variety of ways across Pharma and Biotech. The poster describes the capabilities of the Databricks platform from data ingestion through processing and advanced analytics leveraging Graph computations and Machine Learning spanning a number of high-value use cases.

Sabine Schefzick

Director, Oncology & Vaccine R&D BT, *Pfizer*

Dr. Sabine Schefzick is responsible for the successful delivery of Business Technology products, services and processes to achieve successful outcomes for R & D teams in Oncology, Vaccines and their supporting Partner Lines at Pfizer La Jolla and Pearl River. She leads a team of colleagues with expertise in developing state-of-the-art software applications that are flexible and intuitive to use.

Sabine has more than 10 years of experience as a research scientist with a broad background in chemoinformatics, computational chemistry, data analysis/visualization and therapeutic drug research and development. Moreover, she has extensive experience utilizing informatics and science resources and developing innovative applications.
Dr. Schefzick holds a M.S. in Chemistry from the University of Vienna, a Ph.D. in Chemistry from Purdue University followed by postdoctoral fellowship at Pfizer.

Peter Roberts

Manager, Oncology & Vaccine R&D BT, *Pfizer*

Peter Roberts is a Business Partner for Oncology Translational Research, Early Development and Translational Immuno-Oncology, in La Jolla and the Center of Excellence in Precision Medicine (CEMP) in Chile for Pfizer Inc.. In this role he supports computational biologists, clinicians doing exploratory research, biomarker discovery and companion diagnostics. This involves extensive data management for in-house research as well as clinical data coming from external vendors. It has also required the development and implementation of diverse solutions including GCP-compliant LIMS, freezer inventory management systems, cancer genomics analysis applications, and tumor model knowledge management.

Dr. Roberts has a PhD in Microbiology and a minor in Computer Science, with experience as a bench scientist, bioinformatician and informatics manager.

P3: The Tumor Model Compendium: Knowledge Sharing for Immuno-Oncology Hypothesis Testing

Immuno-Oncology is a major focus of Oncology R&D (ORD) at Pfizer, with a large array of diverse data types and associated metadata being exploited from in-house research projects, clinical studies and external data sources. The Tumor Model Compendium (TMC) is being developed to provide a single source that colleagues can use to identify syngeneic or genetically engineered mouse models (GEMM) that match their genotype or phenotype of interest and shares all available knowledge for a model. The TMC takes advantage of legacy applications and data sources that were developed for niche purposes. If a suitable data source was not available for a particular data type it was created. The aggregated data is accessed through an easily navigated interface that currently displays genome, transcriptome, tumor growth, histology, standard of care and clinical metadata. Data types to be added are proteome, metabolome, single and multiplex immunohistochemistry, T-cell receptor, microbiome and fluorescent activated cell sorting (FACS).

Rajiv Pande

President and CEO, *Smpl Bio*

Rajiv Pande is the President and CEO at Smpl Bio.

Prior to joining Smpl Bio, Pande was Vice President Business Development at Bio-techne (TECH), a global life sciences company. Bio-techne in 2014 had acquired CyVek, a biotechnology company where Rajiv was a co-Founder & Vice President Business Development. He was responsible for creating, developing and executing CyVek's commercialization strategy.

Dr. Pande has 20+ years of experience with commercializing products and technologies, and has held numerous leadership, management and research positions, including those at IDEXX Laboratories, Fisher Life Sciences, Pierce Biotechnology and Medical Analysis Systems.

He holds a PhD from the University of Massachusetts, and an MBA from Yale University.

P4: Kratos: Enabling Single Cell Genomics

The diversity or heterogeneity of diseased tissues has biomarker discovery and therapeutic implications, and presents significant challenges in drug development. Single cell sequencing technology, the first significant improvement over traditional bulk sequencing methodology, provides tools needed to address these challenges. While the wet bench segment of single cell sequencing is becoming less expensive and more familiar, the associated data analysis has been severely lagging leaving researchers with large quantities of potentially extremely interesting but unusable data. Kratos Ace, Smpl Bio's fully automated comprehensive genomic analysis platform is the first commercially available application designed specifically to address the single cell data analysis bottleneck. Using Kratos, analysis time of a typical data set is just a few hours, with only minutes of actual hands-on time, as opposed to months. Kratos Ace eliminates the computational complexity of single-cell genomic analysis, empowers researchers to focus on biology and greatly expedites translational research and drug discovery.

Robert Zambon

Chief Scientist, *Booz Allen Hamilton*

Robert Zambon, PhD, a Chief Scientist and the Lead of Booz Allen's Life Sciences R&D Practice, has more than 15 years of experience in management consulting and the life sciences industry. He brings broad healthcare industry experience with deep knowledge and direct experience in R&D operations, clinical research and clinical trial data analysis, manufacturing, sales, and marketing within the pharmaceutical, biotechnology, and medical device sectors.

He has led and supported multiple business, technology, and R&D strategic initiatives across the life sciences industry, including the development and execution of research and data driven strategic initiatives, data integration platforms, data visualization tools, data management solutions, data governance initiatives, the application agile/scrum methodologies outside of software development, and organizational change/stakeholder management frameworks.

Furthermore, Dr. Zambon has direct experiences in the development of therapeutics in the areas of orthopedics and radiological and nuclear countermeasures, as well as specific expertise in stem cell therapeutics, tissue-based therapeutics, immunology, virology, and molecular biology.

Nirav Desai

Chief Technologist, *Booz Allen Hamilton*

Nirav S. Desai is a technology and innovation consultant in Booz Allen's Seattle office with 15 years' experience helping clients in large enterprises plan for and adapt to disruptive technologies and leverage data to transform strategy into action. In this capacity, he serves three distinct roles: (1) he serves as the firm's innovation lead for the Pacific Northwest, developing strategy and build a culture of innovation to foster entrepreneurship across a diverse staff and client base; (2) he is an innovation scout developing and nurturing relationships with strategic partners and innovative startups whose technologies bring value to firm engagements; finally, (3) he builds firm intellectual capital and service offerings specifically in experiential and immersive technologies (augmented reality, virtual reality, brain-computer interfaces, etc.) with a focus on connecting external innovation to client challenges.

Mr. Desai has contributed to and led multi-million project as an individual performer (system architect, data scientist, software developer) and as a technical manager. Through his career, he has worked on projects in the defense, national security, global health, technology, civil, and financial sectors. Prior to joining Booz Allen, Nirav worked for various startups in Washington, DC and Austin, TX.

Mr. Desai contributes back to his community through being a Civic Council member for the University of Washington Masters of Arts in Applied International Studies, a Start-up Mentor for TechStars Seattle and Nine Mile Labs, and the Innovation Working Group co-chair for the Pacific Northwest Economic Region. Nirav received a BS in Computer Science and a BA in Philosophy and Mathematics from the University of Texas at Austin.

P5: Augmenting the Reality of Healthcare

The need to access, analyze, and act upon patient related healthcare data has always been a key element in successful patient care. With new data, technologies, and approaches emerging on a regular basis, together with tighter than ever restrictions on time per patient, providers are increasingly being put into a position where it's simply not possible to review – or even access – all data available on a patient when making critical decisions. Through the use of augmented reality, available through devices such as the Microsoft HoloLens or even the Surface Tablet, physicians can access and analyze any patient related information desired and use that information to drive rapid decisions that would otherwise require the time and effort of accessing multiple systems (e.g., imaging, ELN, clinical decision support, etc.) to come to the same decision. In addition to access comprehensive patient information in one place, augmented reality can provide visual summaries of a patient's status to quickly draw healthcare providers' attention to the most relevant information or to time-sensitive issues. By providing access to integrated comprehensive patient data in an intuitive and controlled way, augmented reality and associated data analysis capabilities are poised to revolutionize healthcare and clinical research across the world.

Lina Nilsson

COO, Enlitic Inc.

Lina Nilsson, PhD is COO at Enlitic, an artificial intelligence startup founded to distill actionable clinical insights from large quantities of unstructured medical data.

Most recently, Dr. Nilsson was the Innovation Director at one of the largest centers at the University of California, Berkeley, where she helped spin out new technologies and oversaw a portfolio of over 90 technology projects in medicine, infrastructure, and communications, across 40 countries.

Before this, Dr. Nilsson worked on CellScope, a novel cellphone-based technology for automated disease diagnosis. Lina has been a member of the Global Health Advisory Board for Investors' Circle and is the co-founder of Tekla Labs, an open-science hardware collaborative.

Dr. Nilsson has been recognized on MIT Technology Review's "TR35" annual list of the world's top 35 innovators under the age of 35. Her writings have been published in the New York Times, Washington Post, Science, and Make Magazine. She is a biomedical engineer and holds a doctorate from ETH Zurich.

P6: Deep Learning Technology in Healthcare

Deep learning is a form of artificial intelligence that is inspired by the workings of the human brain. Networks of artificial neurons analyze large datasets to automatically discover underlying patterns, without human intervention. To date, the technology has commercial been mostly use in applications such internet commerce and finance. This presentation will discuss how deep learning works and how it can be used in healthcare.

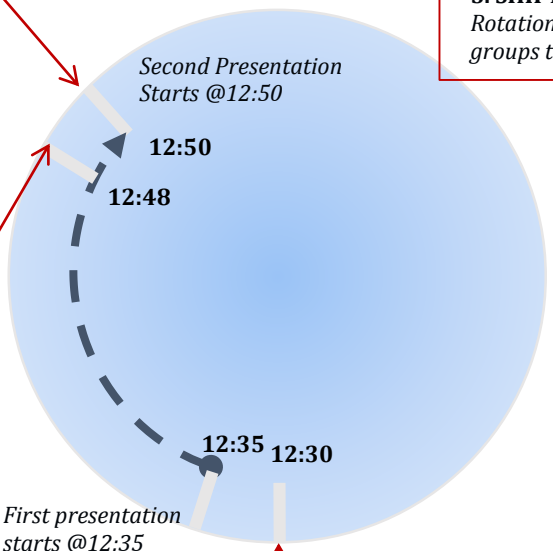
For example, Enlitic's deep learning networks examine millions of images to automatically learn to identify disease. Deep learning technology can incorporate a wide range of unstructured medical data, including radiology and pathology images, laboratory results such as blood tests and EKGs, patient histories, and electronic health records (EHRs). This richness allows higher accuracy and deeper insights for every patient case or clinical trial.

We will discuss how deep learning works and how it can be used in diverse R&D and diagnostic applications such as patient triage and cohort identification, real-time clinical decision making, screening programs, population- and preventative-care, and retrospective analysis.

SESSION STRUCTURE

4. LONG RING @12:50pm
PRISME Forum staff will ring to announce presentation closing and movement of color-coded groups to the next

5. SHIFT TO NEXT
Rotations will involve shift of participants' groups to the next poster on their right.



3. SHORT RING @12:48pm
PRISME Forum staff will ring once to announce 2 minutes to wrap-up

2. CONGREGATE @12:35
Delegates are invited to identify the color of their lanyard and match to rotation called out by staff: "Rotation 1, 2, …n".

1. INSTRUCTIONS @12:30pm
Session Chair will invite participants to take their seats. Chair will open the session by introducing the presenters, their posters, along with the session structure and flow.

FIRST SET OF ROTATIONS:

ROTATION 1 - 12:35	ROTATION 2 - 12:50	ROTATION 3 - 13:05
P1 – Orange	P1 – Yellow	P1 – Red
P2 – Blue	P2 – Orange	P2 – Yellow
P3 – Green	P3 – Blue	P3 – Orange
P4 – Purple	P4 – Green	P4 – Blue
P5 – Red	P5 – Purple	P5 – Green
P6 – Yellow	P6 – Red	P6 – Purple

BREAK FOR LUNCH

SECOND SET OF ROTATIONS:

ROTATION 4 - 14:15	ROTATION 5 - 14:30	ROTATION 6 - 14:45
P1 – Purple	P1 – Green	P1 - Blue
P2 – Red	P2 – Purple	P2 – Green
P3 – Yellow	P3 – Red	P3 – Purple
P4 – Orange	P4 – Yellow	P4 – Red
P5 – Blue	P5 – Orange	P5 – Yellow
P6 – Green	P6 – Blue	P6 – Orange

POSTER ROTATIONS *(lanyard colors)*

ORANGE	
Edsel Calliste-David	*Astellas*
Beatrice Chapuzet	*Servier/Praxis*
David Christie	*Amgen*
Devendra Deshmukh	*Merck*
Ping Du	*Celgene*
Martin Erkens	*Roche*
Sanjay Kalghatgi	*Sanofi*
Samuel Shukovsky	*Boehringer-Ingelheim*
Sandor Szalma	*Takeda*
BLUE	
Mathias Asp	*Novartis*
Noah Craft	*Science 37*
Pete Dhillon	*Daiichi-Sankyo*
Andreas Friese	*Bayer*
Philip Hajduk	*AbbVie*
Daniel Heighway	*Eli Lilly and Company*
Klaus Hofenbitzer	*Celgene*
Abhijit Lele	*Databricks*
Thomas Løngborn-Jensen	*Novo Nordisk*
GREEN	
Jim Doehrman	*Sierra Ventures*
Joel Ekstrom	*Ionis*
Frank Malta	*Celgene*
Jim McGurk	*Daiichi-Sankyo*
Nandish Poluru	*Bristol-Myers Squibb*
Michael Robbins	*Celgene*
Alex Schuleit	*H. Lundbeck*
Kim Smyth	*AstraZeneca*
David Wilson	*UCB*
PURPLE	
Andrew Allen	*Regeneron*
Cathy Critchlow	*Amgen*
Peter Gassner	*Veeva Systems*
Lars Greiffenberg	*AbbVie*
Martin Leach	*Alexion*
Sean Liu	*Takeda*
Simon Roach	*GSK*
Jin Ruan	*Celgene*
Abhishek Shankar	*HCL America*
Ashok Upadhyay	*Otsuka*
RED	
John Apathy	*Celgene*
Richard Crook	*Ionis*
Eric David	*Organovo*
Hugo Delgadillo	*Celgene*
Tomoyuki Matsunaga	*Takeda*
Carl Ruel	*Sunovion*
Susie Stephens	*Pfizer*
Hal Stern	*Merck*
Etzard Stolte	*Roche*
Boris Umylny	*Smpl Bio*
YELLOW	
Dan Chapman	*UCB*
Gene Dantsker	*Qualcomm Life*
Matteo di Tommaso	*Biogen*
Olivier Gien	*Sanofi*
George Goldsmith	*Otsuka*
Henry Levy	*Veeva Systems*
Birgitte Mathiesen	*Novo Nordisk*
David Sedlock	*Takeda*
Pascual Starink	*Celgene*

SESSION IV
PLENARY PRESENTATIONS

Session Chair: Kim Smyth

Technology Innovation Director, *AstraZeneca*

Kim Smyth is Technology Innovation Director in the Silicon Valley Office of the CTO for AstraZeneca, where she leads a team that is scouting and developing proof-of-concepts with new technologies and companies across the Pharmaceutical development and commercial value chain.

Ms. Smyth has twenty years of cross-industry experience in business strategy and operational roles, focusing on large companies where technology is driving significant business disruption. She holds an Engineering degree from the University of Waterloo and an MBA from the Stanford Graduate School of Business.

Cathy Critchlow

VP, Center for Observational Research, *Amgen*

As Head of the Center for Observational Research (CfOR), Dr. Critchlow provides operational and strategic leadership for the design and conduct of observational research within Amgen. The CfOR Real World Data (RWD) Platform provides widespread access to patient health data and visualization and analytic tools based on innovative technologies to aid teams in the generation of real world evidence in support of drug development and commercialization of Amgen products.

Dr. Critchlow joined Amgen in 2004 where she led a number of Therapeutic Areas within Global Epidemiology prior to her being named Head of CfOR in 2012. Prior to joining Amgen, Dr Critchlow was a faculty member in Epidemiology at the University of Washington. Dr. Critchlow was a member of the Endocrinologic and Metabolic Advisory Committee of the Food and Drug Administration and has served on a number of research review committees for the National of Institutes of Health.

Dr. Critchlow earned her bachelor's degree from Stanford University, and both her master's degree in biomathematics and her doctorate degree in epidemiology from the University of Washington. Dr. Critchlow is an Affiliate Professor of Epidemiology at the University of Washington and a Fellow of the American College of Epidemiology.

Real World Evidence Generation: Preparing for the Future

Regulators, industry trade associations and health policy groups are dramatically intensifying the focus on real world evidence to inform decision-making. Both pre-market and post-market observational studies have a growing role in supplementing clinical trials in regulatory submission packages. Payers are increasingly demanding replication of clinical trial results in their insured populations to enable reimbursement. Pharma companies are recognizing that fully leveraging real world data (RWD) brings substantial value, cost-efficiencies and enterprise-wide synergies across the product lifecycle. Investment in technology, analytic tools, and a comprehensive data strategy are required to harness the power of RWD to generate impactful business insights and required evidence. In this presentation, a RWD platform and infrastructure designed to meet the challenges and needs of internal and external stakeholders in the face of a rapidly changing landscape will be described and discussed.

Eric David

Co-founder & Chief Strategy Officer, *Organovo*

Eric David, MD, has more than 15 years of experience in biomedical research and product development. He played a critical role in the commercial translation of 3D bioprinting as a founder and early director of Organovo, Inc.

Dr. David was most recently associate partner at the consultancy McKinsey & Company, where he served private equity, pharmaceutical, biotech, diagnostic, and medical device clients to support pipeline and R&D strategy, as well as market entry strategy.

Prior to his time at McKinsey, Dr. David served as a freelance consultant to the Department of Health and Human Services in the use of genomic technologies for early detection of pathogens for public health preparedness.

He completed his residency in Internal Medicine at New York Presbyterian Hospital, where he served as Assistant Chief Resident and received the Dick Bowman Award for scientific endeavor and dedication to patient care. He was also Assistant Professor at The Rogosin Institute, adjunct faculty at The Rockefeller University, and a lecturer in Medicine at Weil Cornell Medical College.

Dr. David received his MD from Columbia University College of Physicians and Surgeons, his JD from Columbia University School of Law, and a BA in Physics and Fine Arts from Amherst College. He is board certified in Internal Medicine and admitted to the Bar in New York State.

Changing the Shape of Preclinical Research and Clinical Practice Through 3D Bioprinted Organs

Conventional two-dimensional (2D) human cell culture and animal models have at best offered widely varying and inconsistent abilities to detect preclinical safety and efficacy. In the past 25 years alone there have been at least 170 phase III or post-market failures for safety or lack of efficacy, about 30% of which were for hepatotoxicity alone. These failures have spurred tremendous efforts to refine the traditional preclinical paradigm through the invention of new high-throughput assays, model systems, and in silico modeling tools.

Three-dimensional (3D) organ models have sought to bridge the long-standing gap between simple 2D in vitro systems and the human response by recapitulating the complex, multicellular interactions present within an organ. 3D bioprinted in vitro models offer a unique ability to look at biochemical, nucleic acid, and mass spec data, and critically at histologic endpoints in architecturally correct, fully human functional tissues. One advantage identified in 3D organ models has been the ability to extend the in vitro culture period. 3D liver models have demonstrated sustained viability and functionality up to four weeks or more, thus expanding abilities to study chronic effects in an in vitro system. The ability to model drug-induced or disease mediated steatosis or fibrosis, as well as providing a platform for immunohistochemical assessments, prior to investigation of a compound in clinical trials provides greater clinical predictive value than existing methods. We will explore specific examples from liver, kidney and other tissues, both in efficacy and toxicology and discuss the advantages and disadvantages of different 3D culture platforms.

SESSION V
MEETING SUMMARY & AWARDS

Session Chair: Martin Leach

VP, R&D IT, *Alexion Pharmaceuticals*

NOTES