



3<sup>rd</sup> Annual

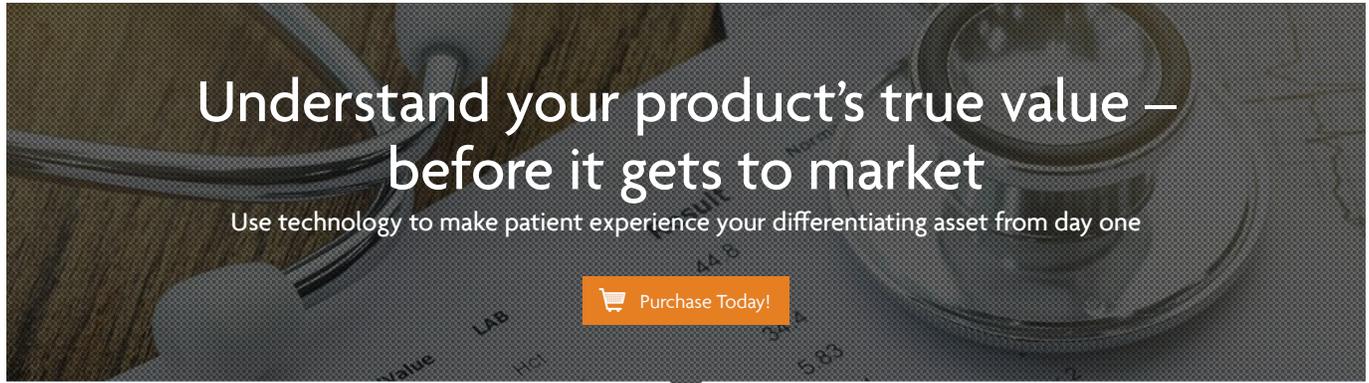
# Data & Technology in Clinical Trials USA

Philadelphia, USA

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## 2017's speakers included:



**Aditi Kumar**  
Amgen  
Executive Director,  
Clinical Systems



**Brooks Fowler**  
AbbVie  
Global Head of Data  
Sciences



**Jyotsna Mehta**  
Alkermes, Inc.  
Director, Economics  
Value Evidence and  
Outcomes



**Pablo Lapuerta**  
Lexicon Pharm...  
Executive Vice President  
and Chief Medical  
Officer



**Sam Hume**  
CDISC  
Head of Data Exchange  
Technologies



**Kannan Natarajan**  
Pfizer  
Global Head of  
Biometrics and Data  
Management



**Aman Thukral**  
AbbVie  
Assistant Director,  
Strategy and Innovation



**Sarah Krug**  
CANCER101  
CEO



**Mohammed Ali**  
Janssen  
Director, R&D  
Operations and  
Innovation Leader



**Robin Heiskell**  
Bristol-Myers S...  
Associate Director,  
Strategic Clinical  
Relationships



**Christopher Pitc...**  
Teva  
Director, Clinical Trial  
Innovation



**Raj Nimmagadda**  
Novartis  
Director, Global Head -  
Data Sciences &  
Standards, Analytics

[See Who Spoke at Last Years Event](#)

Re-design clinical trials so they don't just determine safety and efficacy but also provide key information about patient experience of a drug in order to bring better products to market, quicker.



From cost-center to revenue-generator: turn your clinical trials from an expensive burden into a differentiating asset

- **Minimise the need for post-marketing trials:** incorporate live patient data into your processes to improve the quality of products before launch
- **Improve quality of data and save time** by automating and streamlining processes for sites
- **Enhance patient engagement and retention** with new technologies that reduce the burden
- **Build smarter, more effective strategies** by combining big data with sophisticated analytics and real-time feedback

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**Usable patient feedback shouldn't wait for after a product launch. It's time to embrace data.**

As patients become more engaged in healthcare decisions, they're generating huge amounts of data. If you're not collecting this feedback, analyzing it and putting it to good use, you're missing an opportunity to redefine your products. During the 2nd annual Data and Technology in Clinical Trials Summit, you'll learn how to focus on and make use of the most important data at your disposal to create better products with accurate dosage information from day one.

By accessing the data streams at your fingertips, you'll ensure that your trials don't just efficiently determine safety and efficacy. They'll also provide you with key information you need to bring better products to the market.

The end result will be more efficient trials, shorter and more cost-effective development processes, and a product that launches with the benefit of genuine, real-world feedback to help you position it correctly. In short – it'll give you a real competitive advantage.

Join us to learn from real-world implementations of new data gathering and analysis methods, and to see how new technology and data can be used to lead pharma forwards into a future filled with cost-effective trials, high quality products and satisfied customers.

**Our Track-Record of Proven Success**



of our attendees call our sessions "essential" to their future success



of our attendees say that will likely return next year



rated the program very well run

### What our Delegates are saying



“Great speakers. Terrific format. Well-organized. Relevant and compelling topics”

CEO, CureClick

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Caitlin Champion

Global Project Director  
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## 2017's High Profile Speaker Line-up



### Aditi Kumar

Executive Director, Clinical Systems, **Amgen**



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Aditi Kumar has worked in the pharmaceutical and biotech industry since 1996. In her current role, she works closely with the heads of Global Regulatory Affairs and Safety, Global Development Operations, Global Biostatistics, Center for Observational Research, and VP of R&D Informatics to provide operational and strategic leadership in support of Amgen's worldwide initiatives in clinical development, real world data, pharmacovigilance, and regulatory filings.

In Aditi's first role at Amgen, she was responsible for developing and executing IS strategy for Amgen's Drug Discovery and Translation Sciences functions. She delivered several innovative solutions, including Amgen's first electronic notebook for Medicinal Chemistry.

In 2007, Aditi was assigned to lead the Global Regulatory Affairs and Safety IS team. Aditi established the strategy for reengineering global pharmacovigilance processes and technology, and delivered an end-to-end automated ecosystem for Safety case management and signal detection.

Aditi has held key positions in Amgen's Scientific Affairs where she led the Risk Evaluation and Mitigation Strategy (REMS) operations and in Enterprise Technology Services where she was responsible for IT service management, systems Run operations, and global service desk.

Prior to joining Amgen in 2002, Aditi worked at Bristol Myers-Squibb R&D IS and at Union Pacific Railroad IT.

Aditi holds a Bachelor of Arts in Computer Science from the University of Minnesota, Twin Cities, and a Bachelor of Arts in English Literature from Delhi University, India.



### Pablo Lapuerta

Executive Vice President and Chief Medical Officer, **Lexicon Pharmaceuticals**



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I liked that it was of a decent size but small enough that there could still be dialogue.

**Sr. Director, Quintiles**

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Dr. Lapuerta has been Chief Medical Officer at Lexicon Pharmaceuticals since 2011. He has 20 years of pharmaceutical industry experience in roles including clinical development, global medical affairs and outcomes research. He has overseen clinical trials in cardiovascular disease, endocrinology, gastroenterology, ophthalmology, neurology, immunology, and oncology. Previously he was a vice president at Bristol-Myers Squibb in clinical development and served as Chief Medical Officer at Cogentus Pharmaceuticals. He has published on a wide range of topics including clinical trials, drug safety, epidemiology, health economics, and quality of care. He is a graduate of Harvard College and Harvard Medical School.



### Brooks Fowler

Global Head of Data Sciences, **AbbVie**

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Brooks Fowler is the global head of data sciences at AbbVie. Brooks is specifically accountable for data management operations, clinical informatics and clinical sample management operations. Brooks began his career in pharma with G.D. Searle in 2000. He joined AbbVie in 2003 as a section manager of clinical data management. Over the course of the last thirteen years, Brooks and the AbbVie team have designed and implemented enterprise solutions for EDC, ePRO, IRT, CDR and several other systems related to clinical data

abbvie



### Melva Covington

Principal and CEO, **AGAPE Strategic Solutions, LLC**;  
Formerly Senior Director, Head of Field Based Medical Strategy, **Sanofi**

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Dr. Covington is currently Principal and CEO for AGAPE Strategic Solutions, LLC, which focuses on research, strategic planning and execution of engagement strategies for leaders in healthcare, education and social services. She served as Senior Director, Head of Field Medical Strategy in Diabetes Cardiovascular Disease at Sanofi from August 2016 to January 2017. She has held various leadership positions within Global R&D and Medical Affairs at Sanofi since 2010.

Her leadership skills, expertise and experience in public health, health outcomes, market access, clinical operations and business management have spanned over 20 years, covering the full range of lifecycle development and numerous therapeutic areas. Her vision is to apply these skills in an integrated manner to strategically address complex issues within the healthcare ecosystem. Much of her work focuses on population-based disparities and cultural competency in health systems.

Prior to joining Sanofi, Melva led health outcomes teams both globally and in the US at Lilly and Roche Labs. She is passionate about using integrated data and stakeholder insight as to context to inform targeted solutions to improve health outcomes across diverse patient populations. Her undergraduate degree in Politics and Economics from The Catholic University of America is combined with a Masters of Public Health and Ph.D. from the University of North Carolina at Chapel Hill and MBA from Cornell University. Melva has authored numerous publications and is an impassioned public speaker.



### Kannan Natarajan

Global Head of Biometrics and Data Management, **Pfizer**



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Kannan Natarajan is currently Head of Global Biometrics and Data Management.

Prior to joining Pfizer, Kannan was Senior Vice President and Global Head of Oncology Biometrics and Data Management at Novartis Pharmaceuticals. Kannan has been in the pharmaceutical industry for over 20 years, working across various therapeutic areas and in particular Oncology, over the last 10 years. At Novartis, Kannan was part of the Oncology Development Leadership Team managing the oncology development portfolio, contributing to the global development strategy and to the approvals of several major drugs. Kannan also served as the co-chair of the Protocol Review Committee, in conjunction with the Head of Development. During Kannan's tenure at Novartis, he was instrumental in managing the growth of Development Operations within India, consisting of multiple line functions within global developments. Prior to Novartis, Kannan worked at Bristol-Myers Squibb where he served as the Biostatistics and Statistical Programming therapeutic area head for Immunology, Cardiovascular and Metabolics/Endocrinology, supporting several major global submissions and approvals.

Kannan holds a PhD. Degree in Statistics from the University Florida.



### Raj Nimmagadda

Director, Global Head - Data Sciences & Standards, Analytics, **Novartis**



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Raj has more than 15 years of experience in a management role and have built large teams supporting Data Science and Analytics, Clinical Trial Operations, Data Management and Data Base Programming in the global clinical development organizations.

Raj is an experienced Management professional with deep expertise in data management and leading business change/transformation projects & process improvement projects to improve operation productivity through the introduction of new technologies, systems, and processes to tools.

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### Sam Hume

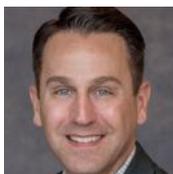
Head of Data Exchange Technologies, **CDISC**



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Sam is the Head of Data Exchange Technologies for CDISC where he leads several technical projects on the SHARE team and co-leads the XML Technologies Team. Sam has over 20 years of work experience in clinical research informatics. Previously, he worked as Vice President of SHARE Technology and Services at CDISC, Director of IS Architecture at AstraZeneca, VP of Technical Operations at Phoenix Data Systems, and Chief Technology Officer at CB Technologies.

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### Christopher Pitcherella

Director, Clinical Trial Innovation, **Teva**



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Chris is currently the Director of Clinical Trial Innovation in the Global Clinical Operations organization sitting within the Global Specialty Development division of Teva. Chris' main accountabilities are being a key driver and influencer of clinical trial innovation opportunities. Providing focused efforts and leading transformation projects that drive scale on the use of healthcare data and technologies that offer novel approaches to clinical trial design, feasibility, recruitment, trial operations, supporting site and patient centricity, quality oversight, and overall execution of clinical trial programs. Chris has over 15 years of experience in pharmaceutical development, progressing through diverse roles of increasing responsibility in the areas of clinical operations; sourcing & procurement; project management; and alliance management. Chris has a BS in Business Marketing and an MBA with a concentration in Management Information Systems from Stockton University, as well as an MS in Clinical Research Organization and Management from Drexel University.



### Aneesh Chopra

President and former (and first) U.S. Chief Technology Officer, **NavHealth**



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Aneesh Chopra is the President of NavHealth, an open data intelligence service launched by Hunch Analytics, a "hatchery" he co-founded incubating ideas that improve the productivity of health and education markets.

From 2009-2012, he served as the first U.S. Chief Technology Officer and prior to that, as Virginia's 4th Secretary of Technology. His public service focused on better public/private collaboration as described in his book, "Innovative State: How New Technologies can Transform Government."

In 2011, he was named to Modern Healthcare's list of the 100 Most Influential People in Healthcare and in 2008, to Government Technology magazine's Top 25 in their Doers, Dreamers, and Drivers issue. He is a Member of the Council on Virginia's Future, earned his master's degree in public policy from Harvard Kennedy School in 1997 and his bachelor's degree from The Johns Hopkins University in 1994.



### Mohammed Ali

Director, R&D Operations and Innovation Leader, **Janssen**



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Mohammed (Mo)Ali is currently a Director within the R&D Operations and Innovations group at Janssen Pharmaceuticals. Mo previously served as a Global Program Manager within the digital development group and Strategic Program Office at Novartis, responsible for several "E" initiatives within the Digital Health Arena. These programs aimed to serve the needs of patients by not just ensuring the support of the execution of the trial delivering the novel therapy but by also leading efforts in creating a digital footprint and platform which would assist in the overall tracking, delivery of the trial for the sponsor, while enriching the patient experience.



## Jaydev Thakkar

Director, Technology Strategy and Innovation, **Amgen**



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Jaydev is responsible for the technology strategy and innovation for discovering, delivering and managing Amgen's therapies. His responsibilities include developing "beyond the therapy" strategy to maximize product value and patient outcomes across patient journey (Clinical Development through product launch and post-marketing) in partnership with cross-functional product leadership teams. His group leads discovery, evaluation, selection and execution of novel platforms, technologies and open innovation capabilities that encompass diagnostics, drug formulations, devices and digital health. Also, he is responsible for shaping innovation strategy and roadmaps across functional innovation groups and corporate Strategy and Innovation team.

Previous experiences include head of IT roles supporting wide spectrum of R&D business functions globally, including Clinical Operations, Clinical Data Management, Development Design Center, Biosimilars, Scientific Affairs (Medical Information, Medical Writing, Regional Medical Liaisons), R&D Portfolio and Pipeline Planning, Safety, Regulatory Affairs etc. His responsibilities included defining Amgen's Clinical IT vision, managing execution of IS portfolio with a multi-year roadmap, and identifying innovations in health care industry that Amgen can leverage in Clinical Development such as Digital Health, Mobile Apps, wearables & sensors, Virtual/Remote trials, Real World Data etc. Over 25 years' experience developing and applying technology for finance, telecom, manufacturing and Life sciences industry.

Jaydev is passionate about improving public health and welfare with innovative solutions and new business models.



## Aman Thukral

Assistant Director, Strategy and Innovation, **AbbVie**



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Aman Thukral is an Assistant Director, Strategy & Innovation in Development Operations at AbbVie. He has over ten years of experience in clinical development, technology planning & business-technology alignment. In his current role, he is responsible for eClinical strategy, piloting new technology initiatives & digital partner for patient engagement group. Before this position, he had worked in Deloitte, Cognizant & GlaxoSmithKline at various levels



## Robin Heiskell

Associate Director, Strategic Clinical Relationships, **Bristol-Myers Squibb**



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Robin Heiskell, RN, is an Associate Director/Relationship Lead for Bristol-Myers Squibb's Strategic Clinical Relationship team within Global Clinical Operations. She first joined BMS in 1998 as a regionally based Site Monitor and has worked on a variety of innovation and technology initiatives throughout her career. She currently leads a "How Might We" team focused on integrating the site and patient voice as part of our clinical trial capabilities.

Robin's interest in clinical trials began while she worked as a Trauma/Critical Care Charge nurse. Her research career began in 1989 at a large, academic level one trauma center. Since then, she has worked in both inpatient and outpatient trials as a Research Nurse Coordinator and as a regionally based site monitor.

Robin received her degree in Nursing from Clark College and her BS from George Washington University.

Her interests include world travel, athletics, music and spending time outdoors.



### Jyotsna Mehta

Director, Economics Value Evidence and Outcomes, **Alkermes, Inc.**

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Jyotsna Mehta is Director, Economics Value Evidence and Outcomes at Alkermes. Her responsibilities include providing strategic HEOR capabilities and insights to maximize access and uptake at launch and throughout the lifecycle of Alkermes products. Jyotsna has worked in the pharmaceutical industry since 2008, including positions of increasing responsibility at Astra Zeneca, Sanofi Aventis, EMD Serono in multiple therapeutic areas. Prior to this, she has worked at FDA and Harvard Medical School as a researcher for 8 years. Jyotsna has an M.S. in Pharmacoeconomics and Pharmacoepidemiology and is a pharmacist by training. She has published widely in peer reviewed journals and made presentations to professional organizations and participated in panels and invited talks.



### Tesheia Johnson

Chief Operating Officer of **YCCI** and the Associate Director for Clinical Research for **Yale University School of Medicine**

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Tesheia Johnson, MBA, MHS, is Deputy Director and Chief Operating Officer of YCCI and the Associate Director for Clinical Research for Yale School of Medicine, where she provides leadership and direction in the area of clinical research.

Her career has focused on the development of clinical research programs and support infrastructure. Prior to assuming her current position, she held positions as Assistant Dean for Clinical Research at the University of Vermont College of Medicine and Director of Clinical Trials at the University of Wisconsin-Madison. She has served as a consultant for several academic centers interested in establishing clinical research programs and as a grant reviewer for the National Institutes of Health.

Ms. Johnson is nationally recognized for her expertise in the design and setup of clinical research programs. She has been an invited speaker at many national and international conferences on topics such as developing funding for central support for clinical research, staffing models for clinical and translational research, training programs for research professionals, clinical research regulation, and contracting and budget negotiation. She has served as Chair and co-Chair for several National Clinical and Translational Science Award (CTSA) Consortium Group/Committees. She sits on the external scientific advisory boards for the CTSA at NYU and the Universities of Washington, Oregon, Florida, and Buffalo.





### Jeremy Wyatt

CTO and Sr. VP of Product Development, **ActiGraph**

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Jeremy Wyatt is the Chief Technology Officer and Sr. Vice President of Product Development at ActiGraph, a global provider of physical activity and sleep monitoring solutions for the pharmaceutical and academic industries. After graduating with his electrical engineering degree from the University of Florida, Jeremy spent six years as an embedded systems developer, redesigning hardware systems for military aircraft. He joined the ActiGraph team as a founding member in 2004 and worked with the team to develop one of the world's first FDA class II cleared activity and sleep monitors. Before taking his role as an executive, Jeremy earned his MBA from the University of West Florida in 2010.

Today, Jeremy and the team continue to serve the global academic and pharmaceutical clinical trial market with a presence in 85 countries. Their flagship software platform, CentrePoint, provides clinical trial teams with a secure, centralized platform for deploying and capturing actigraphy data from thousands of patients across multiple countries by leveraging cloud infrastructure and cellular technology.



### Bhaskar Sambasivan

Senior Vice President & Global Head of Markets – Life Sciences, **Cognizant**

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Bhaskar Sambasivan has over 20 years of experience in providing Consulting, BPO and IT services to many large customers. He has been working in the Life Sciences industry for over 13 years helping customers drive large scale transformation programs in IS, R&D and Commercial functions. Bhaskar currently manages the Life Sciences business for North America and UK and maintains senior level client relationships at many of the large Top 10 Pharmaceutical and Medical Devices companies. Prior to Cognizant, he has spent many years in consulting and leadership roles at PricewaterhouseCoopers and product companies like Siebel, Oracle. Bhaskar is also a regular speaker at many Life Sciences industry events and conferences and author of many thought leadership articles in leading magazines and publications.



### Anita Burrell

Founder of the Aurora Project and Principal, **Anita Burrell Consulting LLC**

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More information coming soon...



### Michael Sparozic

TSOM, Leader, Clinical Supplies Chain Operations – Distribution, **Sanofi US**

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Michael Sparozic is the Lead Trial Supply Operations Manager at Sanofi in Bridgewater, NJ. He has worked in the Clinical Supplies field for close to 20 years. He has experience managing a global supply chain including planning, manufacturing, packaging and distribution of the CTM. He is now leading the US efforts for Direct to Patient trails for Sanofi. Michael attended Massachusetts College of Pharmacy and Health and has a B.S. in Pharmacy.





### Patrick Merel

Founder and CEO, **Portable Genomics**

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Dr. Merel, an expert in molecular diagnostics and an early developer of robotics for the automation of molecular diagnostics from forensics to transplantations, is the founder of Portable Genomics, Inc. Previously, he was with Beckman Coulter, Inc., where he helped start the Nucleic Acid Business Center in San Diego. Dr. Merel has built an extensive background in business development and intelligence, and has worked with major IVD (In Vitro Diagnostics) players in Asia, Europe and the U.S. While at the University Hospital of Bordeaux, Dr. Merel was involved in the Biomedical Innovation Platform where he developed the concept of a wireless genomics platform designed to bring genomic data to professionals and consumers. This concept is now part of Portable Genomics, a digital health startup company developing a mobile technology platform to enable the collection and aggregation of personal health data from medical to genomics, including lifestyle, behavior, and IoT data. He received a Ph.D. in Molecular Biology from Bordeaux University.



### Jeanne Barnett

Founding Member of Aurora Project and President/Founder of CysticFibrosis.com, **CysticFibrosis.com**

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Jeanne has served the on line cystic fibrosis community since 1996 at cysticfibrosis.com (<http://forums.cysticfibrosis.com/activity.php>). The community has grown to over 18000 members with 2 million plus saved and searchable messages.

With a pioneering sense of the web's potential Jeanne listens to the patients stories with patience, curiosity, and understanding.

Using Health Opinion Leaders to build the curriculum of the future, she is passionate about improving the lives of this community by helping them to develop ways to keep their drugs organized and safe, their equipment sterilized, and to have the right technology in the form of wearables, apps, and telemedicine.



### Nikhil Gopinath

Senior Solutions Engineer, **Saama**

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Nikhil Gopinath is a Senior Solutions Engineer & Life Sciences Practice Lead for Saama Technologies. His focus comprises of big data architecture and design, data integration, applications of data science in clinical development, and visual analytics. With a background in clinical research and product development of organic nanoparticle conjugate vaccines, Nikhil applies his diverse skill-sets to build data-driven solutions

Nikhil currently partners with organizations to provide innovative approaches and transform business processes. He has earned his B.S. in Biochemistry from North Carolina State University and is currently pursuing a Master's in Biomedical Informatics at Rutgers University.





### Ami Israel

VP, Clinical Operations, **CMED Research**



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Ms. Israel brings over 25 years of multinational experience across the public and private health care sectors to include, Clinical Research, Operations, Program Management, Regulatory Services, Organizational Development, and Change Management. She has led the global adoption of multiple system launches to support operational efficiencies and enhancements to traditional roles within the clinical research environment.

Ms. Israel blends her expertise in building partnerships, management of diverse teams and communications to gain acceptance for changes within clinical research to support quality delivery and integrity of data. Prior to her career within clinical research; she worked across Africa, Eastern Caribbean and Asia managing HIV/AIDs prevention programming and research with NIH, CDC, and USAID funding. Additionally, she ran the CDC's national hotline services for the US and North American territories.



### Ken Light

EVP, Transformation and Professional Services, **OmniComm Systems, Inc.**



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Ken Light is EVP of Transformation and Professional Services at OmniComm Systems, where he oversees projects to support technology transfer, integration, training, migration and business process improvement for the global Life Sciences community. Ken is also a subject matter expert and frequent presenter at industry conferences related to clinical trial technologies and process optimization.

Prior to joining OmniComm Systems, Ken oversaw similar clinical strategy and technology consulting practices for Oracle Corporation, BusinessEdge Solutions, and First Consulting Group. For the past twenty years, Ken has delivered technology and business strategy services to the majority of top twenty pharmaceutical manufacturers, along with many smaller health and life sciences organizations.

Mr. Light has an M.S. in Computer Science from Fairleigh Dickinson University, and a B.S degree from the State University of New York at Binghamton.

## Representing the patient voice: how to improve patient access and experience of trials via new technologies



### Ide Mills

lung cancer survivor, patient advocate, health educator and patient communication specialist

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More information coming soon...



### Cynthia Chmielewski

Blood cancer survivor, trained mentor, advocate and Patient Ambassador

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Cynthia Chmielewski attended Rutgers University graduating with degrees in Psychology and Education. Upon her graduation Cynthia secured her first teaching position and immediately fell in love with her chosen profession. Cynthia continued teaching for 28 years until she retired in 2009.

In July 2008 Cynthia was diagnosed with multiple myeloma, a blood cancer, after suffering for two years with debilitating back pain which was wrongly attributed to degenerative disc disease. Cynthia has achieved a very good partial remission by using newly FDA-approved novel targeted therapies. Her disease is now stable. She continues myeloma treatment with a maintenance therapy protocol and is enjoying an excellent quality of life.

Now that she is retired Cynthia is using her passion for education to teach a new group of "students" - myeloma patients, their caregivers and others interested in myeloma. Cynthia is on the board of directors of the Philadelphia Multiple Myeloma Networking Group and on the advisory boards of the Patient Empowerment Network and the Myeloma Crowd Research Initiative. She is a trained mentor, advocate and Patient Ambassador. Using social media to educate is Cynthia's passion tweeting at @MyelomaTeacher (<https://twitter.com/myelomateacher>) and sharing myeloma resources on her MyelomaTeacher Facebook page. Cynthia was the co-founder of the #MMSM TweetChat. She is also an active participant in several online support communities and is a regular panelist on CureTalks Internet Radio Podcast. Ms. Chmielewski has spoken and presented posters on using social media in hematology at several medical conferences including the American Society of Hematology's (ASH) and the American Association for Cancer Research's (AACR) annual meetings. She also received scholarships to attend the AACR Annual Meeting as part of the Scientist-Survivor Program, The American Cancer Society Biennial Survivorship Conference, Mayo Clinic's Social Media Residency, and The Compassionate Care Coalition of California annual meeting. Currently she is a Precision Medicine Advocate for CureForward. Additionally, Cynthia serves as a voting member on the Institutional Review Board at the University of Pennsylvania.



## Sarah Krüg

CEO, **CANCER101**

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Sarah initially joined CANCER101 as a board member in 2009 in a quest to help patients navigate their cancer journey. Driven by the passion to make an impact in patient care and engagement, Sarah has held a variety of roles within healthcare. She previously held the position of Global Education Director in the Medical Education Group at Pfizer, focused on establishing global health care improvement strategies and medical education standards worldwide.

Prior to joining Pfizer in 2001, Sarah spearheaded the development of the Pediatric disease management clinical pathways and conducted clinical research at Memorial Sloan-Kettering Cancer Center. She is on the board of the Cancer Patient Education Network, where she also serves as Research Chair. She is also President of the Society for Participatory Medicine and on the board of the National Organization of Rare Diseases.



In an ideal world: Patients are recognized as change agents in healthcare and empowered as active partners in their care in collaboration with their healthcare team.



## Ron Bartek

President, **Friedreich's Ataxia Research Alliance (FARA)**

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Mr. Ronald Bartek is FARA's Co-founder and President; Chairman of the Board of the National Organization for Rare Disorders (NORD); 4-year member, NIH National Advisory Neurological Disorders and Stroke Council, and former partner and president of a business and technology development, consulting, and government affairs firm.



## Esther Schorr

Co-Founder/Chief Operating Officer, **Patient Power LLC**

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Esther Schorr is co-founder and Chief Operating Officer of Patient Power, a leading online channel for cancer patients and family members. She has worked with her spouse, Andrew, on patient and family education projects for more than 30 years. She has supported him in his cancer journey since diagnosis in Seattle in April 1996. Esther is passionate about empowering "care partners" and is a strong believer that education leads to empowerment and better care. She has spearheaded the development of a Care Partner Center on patientpower.info to help connect care partners with each other for support and information sharing, as well as surface resources to help care partners navigate their special role in the healthcare and advocacy journey. Most recently, Esther is driving a "social listening" initiative in collaboration with an innovative tool partner to provide deep insights about patient and care partner concerns. This insight can be used to target and produce relevant content and support clinical trial recruitment efforts.

Esther's experience as a business and marketing consultant and project manager spans high technology, finance, hospitality, not-for-profit, and health care sectors. Esther has an undergraduate

degree in communications and an MBA, both from UCLA.



## Edward Miseta

Executive Editor, **Clinical Leader and Life Science Leader**

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As an editor of Clinical Leader and Life Science Leader, Ed produces original articles on topics and issues related to clinical research, clinical operations, and sponsor/CRO relationships. He also edits contributed articles and is instrumental in producing two weekly newsletters for Clinical Leader. In addition to his writing responsibilities, Ed also attends industry trade shows and takes part in moderating panel discussions and focus groups.

Prior to joining the Life Science Connect team at Jameson Publishing, he spent 9 years covering the mass storage industry as editor for Business Solutions magazine and the newsletter Mass Storage News.

Ed also spent 10 years in the banking and financial service industries as an auditor, mortgage loan operations manager, and investment consultant, in



addition to spending eight years as a lecturer in economics for his Alma Mata Penn State, where he taught courses in microeconomics, macroeconomics, labor economics, and money & banking.

Ed has a BS degree in Business Economics and a master's degree in Business Administration, both from The Pennsylvania State University.

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## Data & Technology in Clinical Trials USA

2018

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## 2017's Conference Agenda

DAY ONE  
21st February

DAY TWO  
22nd February

FULL AGENDA  
21 - 22nd February

### Day One

09:00 - 09:15	Opening address from chairwoman and event director
09:15 - 09:45	<p>A holistic approach: hear from TransCelerate member companies about how the future of technology and patient experience will be inseparable</p> <ul style="list-style-type: none"> <li>• Learn from the experience of TransCelerate member companies about how to identify areas in which there is pent up demand for innovation and ways to take a holistic approach to systems, process, and people in the implementation of various eSource modalities</li> <li>• Keep overall drivers in mind such as improving patient safety, or improving site and patient experience of clinical trials</li> <li>• Review alternatives from the TransCelerate eSource team to overcome obstacles to optimal eSource implementation</li> </ul> <div data-bbox="214 1335 573 1440">  <p><b>Aman Thukral</b> Assistant Director, Strategy and Innovation <b>AbbVie</b></p> </div>
09:45 - 10:15	<p>View stakeholder engagement strategically to optimize decisions and collaboration across matrix organizations</p> <ul style="list-style-type: none"> <li>• Utilize the principles of Strategic Thinking to achieve alignment for clinical trials and research partnerships</li> <li>• Achieve more targeted and impactful outcomes by building inclusive insights from key stakeholders into engagement strategies and trial design</li> <li>• Learn how disruptive technologies and use of devices are changing patient care and stakeholder engagement within Pharma</li> <li>• "One size does not fit all": Moving towards a more cohesive decision making approach to adapt to a changing healthcare environment</li> </ul> <div data-bbox="214 1860 594 1944">  <p><b>Melva Covington</b> Principal and CEO <b>AGAPE Strategic Solutions, LLC</b></p> </div>

10:15  
-  
10:45

## Coffee Break

10:45  
-  
11:15

## Allow your sites to focus on patient relationships by considering the operational burden of technologies

- Involve your sites in the implementation of new technologies to assess if it's something they're going to be able to work with
- Case study. Co-creation: using key learnings from sites and patients to build meaningful strategies.



**Robin Heiskell**  
Associate Director, Strategic Clinical  
Relationships  
**Bristol-Myers Squibb**

11:15  
-  
11:45

## Leverage big data analytics to enhance clinical trials from planning to execution

- How to analyze data to uncover and address cost and timeliness factors in clinical trials
- Discover the key to enriching key data assets by leveraging a bridge to the real world
- Live Demos: Clinical Development Analytics (Study Monitoring) & Clinical Development Feasibility



**Nikhil Gopinath**  
Senior Solutions Engineer  
**Saama**

11:45  
-  
12:30

## Panel: A guide to collecting data. Make better, faster decisions

- Create a single internal platform for gathering and analysing data
- Build the data standards up front to allow for faster, more accurate reporting
- Learn about the benefits of implementing these platforms to CDISC industry standards to prepare yourself for an increasingly industry approach

MODERATOR:



**Sam Hume**  
Head of Data Exchange Technologies  
**CDISC**



**Jeremy Wyatt**  
CTO and Sr. VP of Product  
Development  
**ActiGraph**



**Raj Nimmagadda**  
Director, Global Head - Data Sciences  
& Standards, Analytics  
**Novartis**



**Jaydev Thakkar**  
Director, Technology Strategy and  
Innovation  
**Amgen**

12:30  
-  
13:30

## Lunch Break

13:30  
-  
14:15

## Panel: Recognize why patients are engaging with their own health and how you can become a trusted partner in this

- Improve the care of a patient at the same time as gathering important medical data via the use of apps
- Understand any obstacles that exist to implementing a fully digital engagement strategy

MODERATOR:



**Edward Miseta**  
Executive Editor  
**Clinical Leader and Life Science  
Leader**



**Sarah Krüg**  
CEO  
**Cancer101**



**Ide Mills**  
Lung cancer survivor, patient advocate,  
health educator and patient  
communication specialist

**Jaydev Thakkar**

14:15  
-  
14:45

## Improve data accuracy and timeliness in your trials with the use of Electronic Health Records as eSource

- Find out how far the needle has moved since the FDA released their eSource guidance in 2013 with the results of their demonstration project
- Learn about different models of implementation – and which would be most suited for your clinical trials
- Understand the obstacles that still need to be overcome in order to achieve higher quality data, and more efficient, cost-effective trials



**Ken Light**  
 EVP, Transformation and Professional Services  
**OmniComm Systems, Inc.**

14:45  
-  
15:30

## Panel: Better engage patients by designing trials that fit in with the patient’s own experience of their disease

- Incorporate key learnings about the particular symptoms of a disease by tapping into online patient forums/engagement points.
- Understand the overall patient experience of clinical trials via social media listening, so you can build strategies to overcome the general pain points in your protocol designs
- Engage with/collaborate with third-party, patient-centric organizations that are in regular dialogue with patient communities to expand reach of clinical trial information and heighten awareness of participation opportunities

MODERATOR:



**Edward Miseta**  
 Executive Editor  
**Clinical Leader and Life Science Leader**



**Esther Schorr**  
 Co-Founder/COO  
**Patient Power**



**Cynthia Chmielewski**  
 Blood cancer survivor, trained mentor, advocate and Patient Ambassador



**Robin Heiskell**  
 Associate Director, Strategic Clinical Relationships  
**Bristol-Myers Squibb**



**Ron Bartek**  
**FARA**

15:30  
-  
16:00

## Coffee Break

16:00  
-  
16:30

## The 24/7 pharma company: absorb and gain insights from the wealth of consumer health data coming your way

- With greater use of wearable and sensor devices in clinical trials providing feedback around the clock, our new challenge is to effectively integrate this data and gain insights
- Hear from representatives of AbbVie’s leading Data Science group on how to effectively manage the data chain in wearable data integration
- Accommodate trials of the future by creating a wearable-device-agnostic environment



**Brooks Fowler**  
 Global Head of Data Sciences  
**AbbVie**



**Aman Thukral**  
 Assistant Director, Strategy and Innovation  
**AbbVie**

16:30  
-  
17:00

## “Beginning to end”: see your clinical trial data as one continuous life cycle

- Learn how CDISC SHARE contributes to the availability of standards that work together across the clinical research data lifecycle
- Learn how to improve traceability across the full clinical research data lifecycle to include useful visualizations
- Hear about the important work CDISC has been doing on the CTR-XML standard to more efficiently submit to clinical trial registries



**Sam Hume**  
Head of Data Exchange Technologies  
**CDISC**

17:00  
-  
19:30

Networking Drinks

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## Day Two

08:00  
-  
08:55

Registration

08:55  
-  
09:00

Opening address from day 2 chairman

09:00  
-  
09:30

Understand the value to better understand the potential of new technologies

- Avoid investing in one-off point solutions: think about systems, process; platforms; and people holistically
- Get the buy-in: keep overall drivers in mind such as improving patient safety, or improving site and patient experience of clinical trials
- Calculate the business case when the value is incalculable



**Christopher Pitcherella**  
Director, Clinical Trial Innovation  
**Teva Pharmaceuticals**

09:30  
-  
10:15

Co-presentation: Maintain control and ensure greater transparency of data through the emerging standardization of core industry platforms

- Partner with industry peers to build and run common clinical data and clinical management platforms
- Case study: See how Amgen/ Cognizant are helping to bring together pharma to simplify internal processes and drive efficiencies and speed



**Aditi Kumar**  
Executive Director, Clinical Systems  
**Amgen**



**Bhaskar Sambasivan**  
Senior Vice President & Global Head of  
Markets – Life Sciences  
**Cognizant**

10:15  
-  
10:45

Move towards a more app-centred way of working for more flexible and cost-effective trials

- Learn how the first App based new generation clinical data suite can help you to run more efficient and cost-effective trials by giving access to Apps that have been purpose built to deliver the key functionalities your trial needs
- Discover how new methods of data collection and real-time clinical data analytics can improve data visibility and reduce the number of Protocol violators in your trial.
- Work more effectively with your investigators by increasing the transparency of your trials



**Ami Israel**  
VP, Clinical Operations  
**CMED Research**

10:45  
-  
11:15

## Coffee Break

11:15  
-  
12:00

## Panel: Maximize resource allocation through innovative trial design

- Adapt to risks as the trial progresses to gain better quality data about the optimal dosage before approval
- Reduce the number of patients needed to gain approval by only enriching arms where the drug is shown to be working

MODERATOR:



**Jeremy Wyatt**  
CTO and Sr. VP of Product  
Development  
**ActiGraph**



**Kannan Natarajan**  
Global Head of Biometrics and Data  
Management  
**Pfizer**



**Melva Covington**  
Senior Director, Head of Field Based  
Medical Strategy  
**Sanofi**



**Jyotsna Mehta**  
Director, Economics Value Evidence  
and Outcomes  
**Alkermes, Inc.**

12:00  
-  
13:00

## Panel: How to design (more) patient centric trials including technology: lessons from the Aurora Benchmarking Project

- Learn from the experience of clinical and medical affairs peers in the types of patient centric approaches to trial design including the use of technology from the largest survey ever undertaken in the industry
- Case Study: Rethinking clinical supplies - how Sanofi makes it possible for patients to engage through direct shipment and QR codes
- Case Study: The use of a patient controlled digital tool for data collection, sharing and monetization - how Portable Genomics' platform will change the patient to pharma relationship and accelerate the discovery process.

MODERATOR:



**Anita Burrell**  
Founder of the Aurora Project and  
Principal  
**Anita Burrell Consulting LLC**



**Patrick Merel**  
Founder and CEO  
**Portable Genomics**



**Michael Sparozic**  
TSOM, Leader, Clinical Supplies Chain  
Operations – Distribution  
**Sanofi US**



**Jeanne Barnett**  
Founding Member of Aurora Project  
and President/Founder of  
CysticFibrosis.com  
**CysticFibrosis.com**

13:00  
-  
14:00

## Lunch Break

14:00  
-  
14:30

## Don't let anyone misinterpret your patient's experience of a trial. Improve the quality of data by going direct to the patient

- Using mobile devices to gain real-time insights into how patients are progressing in their trials
- Learn how this data can supplement PROs
- Increasing understanding of your product and its benefits earlier in the drug development process to make better commercial decisions like price later on



**Pablo Lapuerta**  
Executive Vice President and Chief  
Medical Officer  
**Lexicon Pharmaceuticals**

<p>14:30 - 15:00</p>	<p><b>E-consent: communicate the value of your trial directly to the patient</b></p> <ul style="list-style-type: none"> <li>• Discover innovative ways of implementing multimedia tech to give the patient a complete overview of the study</li> <li>• Gain access to previously difficult to reach patient populations</li> </ul> <div data-bbox="214 298 297 380">  </div> <p><b>Mohammed Ali</b> Director, R&amp;D Operations and Innovation Leader <b>Janssen</b></p>
<p>15:00 - 15:30</p>	<p><b>The Consumer-Directed Path to Data Exchange and its Implications for Clinical Trials</b></p> <ul style="list-style-type: none"> <li>• Discover the policy, technical, and emerging business model trends that are enabling consumers to take a more active role in connecting their health data with the applications and services they trust</li> <li>• Evaluate the implications for clinical trials and benchmark your strategies to assemble longitudinal patient records for trial recruitment, enrolment and real-world evidence</li> </ul> <div data-bbox="214 695 297 777">  </div> <p><b>Aneesh Chopra</b> President and former (and first) U.S. Chief Technology Officer <b>NavHealth</b></p>
<p>15:30 - 16:00</p>	<p><b>Save time for your investigators by eliminating dual data entry</b></p> <ul style="list-style-type: none"> <li>• Make life easier for your sites: permit your investigators to work into their own EMR systems and pulling the requisite data directly from those</li> <li>• Avoid human intervention with data to minimise errors</li> </ul> <div data-bbox="214 1058 297 1140">  </div> <p><b>Tesheia Johnson</b> COO / Associate Director for Clinical Research <b>YCCI / Yale School of Medicine</b></p>
	<p>Coffee to go or stay!</p>

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