Novo Nordisk & WCG Strategic Discussion

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September 18, 2019

Meet Our Team

Jill Johnston

President, Study Planning & Site Optimization Division

As President of WCG's Site Activation Solutions, Jill is responsible for developing strategy, driving the vision, and delivering for customers as WCG continues to drive ingenuity in the clinical research space as it relates to site identification, selection, and activation. The aim is to deliver transformational site activation solutions that stimulate growth, foster compliance, and maximize efficiency for those who perform clinical trials. With over 25 years in clinical research, Jill is an expert in clinical business strategy, transformation, innovation, pharmaceutical efficiency, and clinical research operations.

Prior to WCG, Jill was the vice president of Vault Clinical at Veeva. Jill was responsible for providing thought leadership, driving development of product and market strategy, and coordinating resources across the customer lifecycle from sales to delivery for eMF, Study Startup and CTMS.

Before joining Veeva, Jill spent the majority of her career at Covance, where she held a variety of strategic roles in clinical operations, project management, and as a Six Sigma Black Belt. She spent the early part of her career running large, global clinical trials in oncology, cardiovascular, metabolic, and neurology compounds. As she moved into more strategic roles, she provided executive level guidance and led a team of scientific, operational, and medical experts to bring about customized, practical and evidence-based solutions.

Jill holds a BSc in Biology from SUNY – Environmental Science and Forestry and is an instructor for clinical monitoring at Mercer County College, supporting Drexel University's Clinical Development Master program. She was previously the founding president of the ACRP Chapter in the Greater Philadelphia area, and is a frequent speaker at industry conferences.

Meet Our Team

Dawn Flitcraft

President, Ethical Review Division

Ms. Flitcraft joined WCG in 2016 as a member of the executive team. She is involved in planning and executing corporate strategies designed to accelerate the company's growth. She collaborates with various stakeholders to ensure that post transaction the necessary people, processes, and technology are in place to achieve success.

Prior to joining WCG, Ms. Flitcraft was chief operating officer and general manager for Keosys Medical Imaging. She was responsible for leading all of the company's business and operational activities in North America, including sales and marketing, business development, financial, and technological strategies.

Ms. Flitcraft has more than 13 years' clinical trial experience leading global project management and operational teams at Bioclinica. She started her career there as director, project management at Bio-Imaging Technologies Inc. but was soon promoted to vice president, client services and later senior vice president, client services at Bioclinica. Her customer engagement skills were further recognized and she was appointed vice president, alliance management.

Before that, Ms. Flitcraft held management positions with Quintiles Intelligent Imaging. In addition, she has more than 10 years' clinical experience in a hospital setting as a nuclear medicine technologist and ultrasonographer.

Ms. Flitcraft earned a BS in nuclear medicine and biology from Cedar Crest College in Allentown PA and she also holds a certification in M&A integration.

Meet Our Team

Diane Carozza

Vice President, Clinical Strategic Solutions

Diane is the Vice President, Client Strategic Services and responsible for the oversight of the delivery of WCG's Predict and Total Feasibility services. Diane comes to WCG from Medidata Solutions where she was a Managing Senior Engagement Consultant responsible for leading the Study Design and Feasibility offerings at Medidata. Diane is a subject matter expert in protocol and operational feasibility, site qualification/selection and the optimization of the business processes relative to technologies that support clinical operations. Diane possesses 25+ years of diverse experience in the pharmaceutical and technology industries where she held various roles across Professional Services, Product Development, R&D, Clinical Operations, and R&D Information Systems.

Prior to joining Medidata, the majority of her career was spent in Clinical R&D and Clinical Operations at Pfizer and subsequently Allergan where she supported Therapeutic Operations and the Site and Study Management organizations in R&D IS and was a lead contributor on the TransCelerate Biopharma Shared Investigator Platform and Investigator Registry initiatives. Diane is an SME in the development and implementation of web-based investigator portals and was the Director of the InnovoCommerce clinical portal solution where she focused on developing technical solutions to optimize study start-up business processes and create efficiencies for sponsors, CROs, and sites.

Meet Our Team

Suzanne Caruso

Vice President, Clinical Solutions

Suzanne Caruso serves as the Vice President of Clinical Solutions for the WIRB-Copernicus Group. In this role, Suzanne oversees WCG's robust suite of transformational solutions and manages the growth, development, and operational strategy relating to these services. She uses her unique expertise to design and develop new applications that positively impact the efficiency of clinical trials. Suzanne is focused on making WCG's pharma and CRO clients successful with innovative solutions that accelerate time to market, improve safety, and boost data accuracy.

Most recently, she served as the associate director of clinical operations, oncology at Novartis. In her previous role, Suzanne oversaw the Study Start-Up, Compassionate Use, Innovation and Informed Consent Departments. This enabled her to enhance innovations for clinical trials and medical functions in support of improving trial efficiency and protection of human subjects.

Her prior experience includes managing the Investigator Initiated Rare Disease Program franchise and individual patient INDs for the Midostaurin program at Novartis. Suzanne was also responsible for leading two of the four full boards while serving as the Senior Institutional Review Board Manager at Mount Sinai School of Medicine.

Suzanne has been featured in industry publications such as PharmaVOICE and CenterWatch and speaks frequently at industry conferences and roundtable events. She received her Bachelor of Arts degree in epidemiology and human geography from Middlebury College.

Meet Our Team

Lindsay McNair, MD, MPH, MSB

Chief Medical Officer

Dr. Lindsay is the Chief Medical Officer for the WIRB-Copernicus Group (WCG). She oversees the physician team within the WCG IRBs, and provides consultation to institutions and pharma/biotech companies on a wide range of issues related to protocol design, regulatory compliance, human subject protection, and ethical policy development (pre-approval access, subject compensation).

Prior to joining WCG, Dr. McNair was a consultant to multiple biopharma companies, providing medical guidance on clinical development strategies and study designs for new drug studies, and medical oversight of all phases of clinical trials. Before becoming a consultant, Dr. McNair was the medical lead for the telaprevir development program at Vertex Pharmaceuticals, with oversight of the phase 1-3 studies.

Dr. McNair is adjunct faculty at Boston University and teaches graduate courses on the scientific design of clinical research studies.

Dr. McNair graduated from the University of Connecticut School of Medicine and trained in general surgery at Boston University Medical Center. She completed her Master's in Public Health at Boston University concentrating in Biostatistics/Epidemiology, and her Master's of Science in Bioethics at Union Graduate College concentrating in research ethics.

Dr. McNair is an associate editor for the Journal of Empirical Research on Human Research Ethics, and serves on multiple committees including the NYU Compassionate Use Pre-Approval Access (CUPA) Working Group, the Human Subjects Review Board of the US Environmental Protection Agency (EPA HSRB), and the Advancing Effective Research Ethics Oversight (AEREO) consortium.

Meet Our Team

Mark Summers

President, Patient Engagement Division

As President of the Patient Engagement Division at WCG and with over thirty years of experience in pharmaceutical and medical device clinical research, Mark is widely recognized as a veteran entrepreneur and thought leader in the area of accelerating clinical trial patient enrollment. He is the founder and CEO of ThreeWire, Inc., and has led the company through the development and patenting of its proprietary model for maximizing clinical trial patient enrollment. His clinical trial experience at both ThreeWire and sponsors covers a wide range of therapeutic indications and patient populations in over forty countries. Prior to founding ThreeWire, Mark held executive leadership positions at two early stage medical device firms where he produced more than $100 million in global growth following completion of extensive clinical trials.

Meet Our Team

Steven Beales

Senior Vice President, Safety Solutions, Scientific and Regulatory Review, WCG

An expert in the field of safety reporting technology, Mr. Beales has 25 years of experience in IT, and has spent over 16 years in the pharmaceutical industry. He joined WCG ePharmaSolutions in 2009 and led implementation of the company's Clinical Trial Portal at Genentech across 100+ countries. In 2015, he led implementation of the Clinical Trial Safety Portal at a top 5 pharma organization, which included a data-driven rules engine configured with safety regulations from those countries, which saved this organization hundreds of millions of dollars. Over 50 million safety alerts have been distributed by these two portals via the cloud.

Prior to joining WCG ePharmaSolutions, Mr. Beales was the Chief Software Architect at mdlogix, where he led the implementation of the CTMS systems for Johns Hopkins University, Washington University at St. Louis, the University of Pittsburgh, and the Interactive Autism Network for Autism Speaks.

Meet Our Team

Tim Schuckman

President, Sponsor & CRO Services

Tim joined WCG in 2012 as the organization's Director of Business Development. He was quickly promoted to Vice President of Business Development within a year and then moved into his current role as President of Sponsor and CRO Services in 2016. In this role, Tim leverages his deep knowledge of the ethical review space to help our clients maximize efficiency in the way they conduct their clinical trials. Prior to joining WCG, Tim led a sales organization at a top linguistics company. Notably, Tim was also the very first fully dedicated business development executive in the IRB space. Tim graduated from Wittenberg University with a BA in Business Management and Marketing.

Meet Our Team

David Forster, JD, MA, CIP

Chief Compliance Officer

Mr. Forster joined Western IRB (WIRB) in 1996 and is currently the Chief Compliance Officer for the WIRB-Copernicus Group (WCG).

A strong advocate for human subject protections, Mr. Forster co-chairs the Secretary's Advisory Committee on Human Research Protections (SACHRP) Sub-Committee on Harmonization. He previously served a four-year term as a member of SACHRP, and was previously a member of the SACHRP Sub-Committee on Inclusion of Individuals with Impaired Decision-Making in Research. Mr. Forster also served on the Certified IRB Professional (CIP) Council.

Mr. Forster has a law degree and a Masters in Medical Ethics from the University of Washington.

Meet Our Team

Nathaniel Katz, MD, MS

Chief Science Officer, WCG Analgesic Solutions

Dr. Nathaniel Katz is considered one of the leading experts of treatment and clinical study design in pain clinical trials. He is a neurologist and pain management specialist with a distinguished career at Harvard Medical School, Brigham & Women's Hospital and Dana Farber Cancer Institute. From 2000-2004 he served as Chair of the Advisory Committee, Anesthesia, Critical Care, and Addiction Products Division, United States FDA, during which time he completed a Master of Science in Biostatistics at Columbia University.

Dr. Katz founded Analgesic Solutions with the mission of modernizing the design and conduct of pain clinical trials to advance the "scientific quality" of pain clinical research, and empower effective treatments for patients. He is the Chief Science Officer at WCG Analgesic Solutions.

Dr. Katz's holds the position of Adjunct Associate Professor of Anesthesia at Tufts School of Medicine. He has completed numerous clinical trials of treatments for pain, both industry-initiated and investigator-initiated, involving pharmaceuticals, non-pharmaceutical analgesics and devices, and has also conducted studies related to opioids, pain, addiction, and other issues related to opioid therapy. Dr. Katz was an Associate Editor at the Clinical Journal of Pain, and Associate Editor (Pain) for the Encyclopedia of Neurological Sciences.

Meet Our Team

Mark G. A. Opler, PhD, MPH

Chief Research Officer, WCG MedAvante-ProPhase

Dr. Opler joined WCG in 2017 as Chief Research Officer at MedAvante-ProPhase. In this role, he directs scientific research and development and leads ongoing studies in psychiatry, neurodevelopment, and other areas of neuroscience.

In addition, Dr. Opler is a faculty member in the Department of Psychiatry at New York University. His academic research focuses on the etiology, phenomenology, and treatment of serious and persistent mental disorders. He is a co-author and developer of several clinical assessment tools, including the SNAPSI, CGI-DS, and NY-AACENT. He is also a contributor to the latest edition of the PANSS Manual©.

Dr. Opler has received research support from the US NIMH, the Brain & Behavior Foundation (formerly NARSAD), the Stanley Medical Research Institute, and the Qatar National Research Fund. He has co-authored more than 50 peer-reviewed publications and has contributed to multiple book chapters and review articles on clinical assessment, research methodology, and mental health.

He received his PhD and MPH from Columbia University and his BSc from SUNY at Stony Brook. He is a graduate of the Psychiatric Epidemiology Training Program at Columbia University and completed his postdoctoral fellowship at the New York State Psychiatric Institute..