

## **AGENDA**

### **Thursday, March 3**

- 9:00 AM      **Arrivals/Light Breakfast**
- 10:00      **Welcome, Introduction, and Objectives**  
Walter Capone  
*Multiple Myeloma Research Foundation*  
*Multiple Myeloma Research Consortium*
- 10:15      **Presentation: Longitudinal Study Overview**  
Kenneth C. Anderson, MD  
*Dana-Farber Cancer Institute, Harvard Medical School*
- Sagar Lonial, MD  
*Winship Cancer Institute, Emory University School of Medicine*
- 10:45      **Working Session: LS Protocol Objectives Review**  
Harish Dave, MD  
*Quintiles Clinical*
- 11:45      **Presentation: Epidemiological Statistics and Observational Trials**  
Ralph D'Agostino, Jr, PhD  
*Wake Forest University School of Medicine*
- 12:15 PM    **Break**
- 12:30      **Working Lunch: Inclusion Criteria, Endpoints, and Data Elements**  
Eric Gemmen, MA  
*Quintiles Clinical*
- 1:00      **Working Session: Patient Journey/Schedule of Events**  
Harish Dave, MD
- 1:45      **Working Session: Molecular Testing and Patient Data**  
Brad Smith, PhD  
*Quintiles Innovation Unit*
- 2:15      **Working Session: Final LS Objectives Review and Approval**  
**Discussion: Other Key Issues and Next Steps**  
Kenneth C. Anderson, MD, and Sagar Lonial, MD
- 2:55      **Wrap Up and Conclusion**  
Kathy Giusti  
*Multiple Myeloma Research Foundation*  
*Multiple Myeloma Research Consortium*
- 3:00 PM    **Adjournment**

**BIOGRAPHIES – FACULTY****Kenneth C. Anderson, MD***Dana-Farber Cancer Institute, Harvard Medical School*

Dr. Anderson graduated from The Johns Hopkins Medical School, trained in internal medicine at The Johns Hopkins Hospital, and completed hematology, medical oncology, and tumor immunology training at the Dana-Farber Cancer Institute. He is the Kraft Family Professor of Medicine at Harvard Medical School; and Director of the Lebow Institute for Myeloma Therapeutics and Jerome Lipper Multiple Myeloma Center, and Vice Chair of the Joint Program in Transfusion Medicine at the Dana-Farber Cancer Institute. Dr. Anderson is chair of the NCCN Multiple Myeloma Clinical Practice Guidelines Committee; a Cancer and Leukemia Group B Principal Investigator; on the Board of Scientific Advisors of the International Myeloma Foundation; on the Board of Directors and Chair of the Scientific Advisory Board of the Multiple Myeloma Research Foundation; and on the Board of Directors and Chair of the Steering Committee of the Multiple Myeloma Research Consortium.

Dr. Anderson has published more than 350 original articles, 250 chapters, and has edited multiple textbooks on both multiple myeloma (MM) and transfusion medicine. His awards include the 2007 American Association for Cancer Research Joseph H. Burchenal Award for Clinical Research, the 2007 ROFEH Distinguished Service Award, the 2007 Champion in Advocacy Award from the American Society of Hematology (ASH), the 2005 Robert A. Kyle Lifetime Achievement Award, the 2004 Johnson & Johnson Focused Giving Award for Setting New Directions in Science and Technology, the 2003 Waldenstrom's award for research in plasma cell dyscrasias, and the 2001 Charles C. Lund Award of the American Red Cross Blood Services. He was named Editor in Chief of *Clinical Cancer Research* in 2007.

His translational research studies focus on B-cell malignancies, especially MM. His contributions include discovery of the first plasma cell reactive monoclonal antibodies; development of an immunophenotyping model for diagnosis and treatment of B-cell malignancies; pioneering novel methods to improve safety and efficacy of autografting and allografting in MM; characterizing the signaling cascades whereby cytokines mediate MM cell growth, survival, and drug resistance in the bone marrow (BM) microenvironment; using oncogenomics and developing *in vitro* and *in vivo* models to identify novel targets and validate therapies targeting the MM cell and its BM milieu; translating these preclinical studies to the bedside in derived Phase I–III clinical trials; and establishing a new treatment paradigm using novel therapies targeting the tumor cell, tumor-host BM interaction, and BM microenvironment to overcome drug resistance and improve patient outcome in MM. His team led both preclinical and clinical trials of bortezomib and lenalidomide, culminating in rapid FDA approval of these agents for the treatment of MM.

**BIOGRAPHIES – FACULTY (CONT)****Walter Capone, MBA***Multiple Myeloma Research Foundation**Multiple Myeloma Research Consortium*

Walter Capone oversees the core business operations of the MMRF and as part of the Executive Committee executes the growth initiatives outlined in the organization's strategic plan. He has 20 years of pharmaceutical and biotechnology leadership experience in the areas of Commercial Development, Operations, Finance, Marketing, and Sales in the United States and internationally. Prior to joining the MMRF, he was the Vice President of Commercial Development and Operations at Progenics Pharmaceuticals. He previously worked at a number of entrepreneurial pharmaceutical and biotechnology ventures throughout the United States and Europe including Trimeris, Triangle Pharmaceuticals, and Cyanamid Benelux. He started his career at leading global pharmaceutical companies including Lederle, Wyeth, and Bristol-Myers Squibb. He received his BA in International Relations from Brown University and he has an MBA in Finance and International Business from Columbia University Business School.

**Ralph D'Agostino, Jr., PhD***Wake Forest University School of Medicine*

Dr. D'Agostino has been the Director of the Biostatistics Core for Comprehensive Cancer Center of Wake Forest University School of Medicine since 2004. He holds a PhD in Mathematical Statistics from Harvard University and is a tenured Professor in the Department of Biostatistical Sciences. Dr. D'Agostino joined the faculty at Wake Forest in 1994, and during these past 16 years, he has become a leader in methodological and collaborative research in both statistical and medical areas. He has been the PI or co-PI for eight federally funded grants or subcontracts and the lead/senior statistician on numerous NCI-funded grants. In addition, he is currently funded as the lead statistician on several externally funded grants that focus on cancer research. He has over 170 peer-reviewed manuscripts in statistical methodology and medical research including cancer.

In addition to the above research accomplishments, Dr. D'Agostino has served/serves on several editorial boards and on numerous review panels for the NIH and DOD, including being a member of the NCI SPORE review panels in 2010 (Feb/Sept) and 2011 (Feb). Dr. D'Agostino has also served on more than 20 data safety monitoring committees, including many with the primary therapeutic agents targeting cancer treatments (ie, XL184-203 A Randomized Discontinuation Study of XL184 in Subjects with Advanced Solid Tumors and XL184-301 An International, Randomized, Double-Blinded, Phase 3 Efficacy Study of XL184 Versus Placebo in Subjects with Unresectable, Locally Advanced or Metastatic Medullary Thyroid Cancer).

**BIOGRAPHIES – FACULTY (CONT)****Harish Dave, MD***Quintiles Consulting*

Dr. Dave was previously Associate Professor of Medicine at George Washington University and Assistant Chief of Hematology and Chief of Laboratory of Molecular Hematology at the Veterans Affairs (VA) Medical Center in Washington, DC. He received his medical degree and completed his internship in internal medicine and surgery at the University of Sheffield Medical School in England. Dr. Dave received his residency training at Royal Medical Postgraduate Medical School System, University of London in England (Hammersmith Hospital, National Hospital for Nervous Diseases, and Brompton Hospital). He then joined the National Institutes of Health in Washington, DC, where he worked on globin gene regulation and gene therapy for Gaucher's disease. Dr. Dave trained in hematology and medical oncology at George Washington University and the VA Medical Center in Washington, DC, and in bone marrow transplantation at Johns Hopkins University Medical Center. He is board certified in internal medicine, medical oncology, and hematology.

He is also a member of several professional societies, including the Royal Institute of Public Health & Hygiene, Institute of Biomedical Sciences, American Federation for Clinical Research, American Association for Cancer Research, American Society for Biochemistry and Molecular Biology, American Society of Hematology, and American Society of Clinical Oncology. With research interests in gene therapy, myelodysplastic syndrome, hematologic malignancies, gene regulation, and tumor immunology, Dr. Dave has served as principal investigator (PI) and co-PI in several clinical studies. He has chaired several local and national VA and NIH research and scientific committees. He has lectured at national meetings and has collaborated on chapters in books as well as authored and co-authored articles and abstracts that have been published in various peer-reviewed journals, such as *Blood*, *Gene*, *Proceedings of the National Academy of Sciences USA*, *American Journal of Hematology*, and *Journal of Cellular Biology*.

Dr. Dave has 15 years of academic hematology-oncology experience during which he served as a PI on pharmaceutical industry-sponsored studies, as well as NCI-sponsored Cancer Group (CALGB) studies. He also was a PI on several investigator-initiated studies prior to joining Quintiles. Additionally, he served as Chairman of a NIH Study Section and also chaired the Research and Development Committee at a major academic medical institution. In the latter capacity, Dr. Dave oversaw all research and IRB-related activity, reviewing and managing over 170 protocols annually. He has over 6 years of industry experience at Quintiles, where he oversees a number of hematology and oncology studies at all phases of drug development, as well as providing drug development strategy and guidance. His areas of therapeutic experience include cancers of lung, breast, colorectal, brain, sarcoma, pancreas, and liquid tumors. He also leads the global therapeutic group for hematology, oncology, and transplantation.

**BIOGRAPHIES – FACULTY (CONT)****Eric Gemmen***Quintiles Consulting*

Mr. Gemmen is a 12-year veteran of Quintiles. His responsibilities include directing statistical data analysis and writing for Phase IV and observational studies, designing and implementing prospective health outcomes studies, and providing senior operations oversight to real-world effectiveness and safety studies for pharmaceutical, biotechnology, and other health care clients. He serves as the Chair of the Design, Development, and Implementation of Patient Registries Working Group for the International Society for Pharmacoeconomics & Outcomes Research (ISPOR) and also serves on the Analysis of Patient Registries Working Group for ISPOR.

Mr. Gemmen works actively in epidemiologic and outcomes research and in performing data analyses to support burden of illness, comparative effectiveness, and safety studies. He has co-authored publications in *Pharmacoeconomics, Disease Management & Health Outcomes, Journal of Medical Economics*, and two large burden of illness studies published in *Gastroenterology* and *Journal of the American Academy of Dermatology*.

Before joining Quintiles in 1998, Eric worked five years at Abt Associates, Inc., where he was involved in research design and data analysis for domestic and international health economic studies for clients such as the Centers for Medicare & Medicaid Services, USAID, and the World Bank. He holds a Master of Arts degree in Economics from Duke University.

**Kathy Giusti***Multiple Myeloma Research Foundation**Multiple Myeloma Research Consortium*

Kathy Giusti founded the Multiple Myeloma Research Foundation (MMRF) in 1998 after being diagnosed with multiple myeloma, an incurable blood cancer. In 2004, she founded the Multiple Myeloma Research Consortium (MMRC). Today, she is CEO of both organizations. Previous to this, Ms. Giusti was a senior executive in the pharmaceutical industry; as a 15-year industry veteran, she held positions at both Merck and G.D. Searle & Co. (now part of Pfizer), where she focused on marketing and new product development.

Ms. Giusti has received numerous awards for her efforts to accelerate biomedical research and drug development, including the American Association for Cancer Research's Centennial Medal, American Society of Clinical Oncology's Partners in Progress Award, Healthcare Businesswomen's Association's Woman of the Year Award, and Harvard Business School's Leadership Award. Her efforts also have been recognized by many notable media outlets, including *The New York Times*, *The New Yorker*, *The Wall Street Journal*, CBS Evening News, and NBC Nightly News. Ms. Giusti has served on several boards, including the Institute of Medicine's National Cancer Policy Board, the Cancer Leadership Council, and IMS Health. Today, she continues to serve on the National Cancer Advisory Board, an appointment she received from President Bush.

Ms. Giusti received her MBA in general management from Harvard Business School and graduated from the University of Vermont magna cum laude with a Bachelor of Science in Biological Sciences.

**BIOGRAPHIES – FACULTY (CONT)****Edward E. Harlow, Jr., PhD***Constellation Pharmaceuticals, Inc.*

Dr. Harlow joined Constellation Pharmaceuticals, Inc., in October 2009 from Harvard Medical School, where he was Professor and Chair of the Department of Biological Chemistry and Molecular Pharmacology and Associate Director of the Dana-Farber/Harvard Cancer Center. Dr. Harlow also serves as a Special Assistant to the Director of the National Cancer Institute.

Dr. Harlow is an internationally recognized leader in cancer biology who is best known for his discoveries regarding the control of cell division and critical changes that allow cancer to develop. Previously he served as Scientific Director for the Massachusetts General Hospital Cancer Center and as Associate Director for Science Policy at the National Cancer Institute, where he helped direct U.S. cancer research planning. Among his numerous scientific honors are election to the National Academy of Sciences and the Institute of Medicine, appointment as Fellow of the American Academy of Arts and Sciences, and receipt of the American Cancer Society's highest award, the Medal of Honor. He has also served on a number of advisory boards, including the Board of Life Sciences for the National Research Council, External Advisory Boards for UCSF, Stanford, UCLA, and NYU Cancer Center, and Scientific Advisory Boards for the Foundation for Advanced Cancer Studies and several biotechnology and pharmaceutical companies, including Onyx Pharmaceuticals, Inc., Alnylam Pharmaceuticals, 3-V Biosciences, and Pfizer Pharmaceuticals.

**Sagar Lonial, MD***Winship Cancer Institute**Emory University School of Medicine*

Dr. Lonial completed his hematology-oncology training at Emory University, and prior to that received his internal medicine residency at the Baylor College of Medicine in Houston Texas. There he spent an additional year as a Chief Medical Resident at the Ben Taub General Hospital as well as the Texas Heart Institute and St. Lukes Hospital.

Dr. Lonial has worked in the field of cancer immunotherapy for a number of years with preclinical and clinical work focusing on dendritic cell function in the context of allotransplantation, and has subsequently focused on developing the B-cell malignancy program with respect to novel targeted agents in laboratory models, as well as early clinical trials. Most recently, Dr. Lonial has focused on combinations of novel agents as therapy for myeloma and lymphoma, particularly evaluating combinations that may result in synergistic inhibition of the PI3-K/Akt pathway. His lab has recently received funding from the MMRF, the Lymphoma Research Foundation, and The Leukemia & Lymphoma Society. He staffs and works both on the bone marrow and stem cell transplant service, as well as in the B-cell malignancy clinic.

He is on the editorial board for *Clinical Lymphoma and Myeloma* and *The American Journal of Clinical Oncology*, as well as an ad-hoc reviewer for *Blood*, *Cancer Research*, *Clinical Cancer Research*, *Haematologica*, *The New England Journal of Medicine*, the *Journal of Clinical Oncology*, *Leukemia*, and other journals. He has authored or co-authored over 100 papers and abstracts, and was recently appointed as Vice-chair for the ECOG myeloma committee and serves on the Steering Committee for the Multiple Myeloma Research Consortium (MMRC).

## **BIOGRAPHIES – FACULTY (CONT)**

### **Brad Smith, PhD**

*Quintiles Consulting*

Dr. Smith currently is a VP of Translational Medicine within the Innovation Group at Quintiles Transnational, the leading CRO supporting drug development throughout the globe. In this position, Dr. Smith supports clinical and biomarker strategies for drug development, as well as the development of innovative tools for targeted drugs and companion diagnostics.

Previously, Dr. Smith led Corporate Development, focused on new diagnostic and clinical partnerships and markets at Cell Signaling Technology, an innovative biotechnology company in the life sciences field. His previous positions at Cell Signaling Technology include management of antibody and clinical assay development departments. Previous to Cell Signaling Technology, Dr. Smith directed product development and production at Santa Cruz Biotechnology, helping to build that company into one of the largest suppliers of research tools for basic research.

Dr. Smith's scientific background includes research positions at Stanford University and the University of California, San Francisco, focused on cellular signaling mechanisms of disease. Dr. Smith holds a doctoral degree from Stanford University and master's and bachelor's degrees from the University of California, Santa Cruz. Dr. Smith resides in Marblehead, MA, with his wife and two young children.

**BIOGRAPHIES – PARTICIPANTS****Jeanne Kowalski, PhD**  
*Winship Cancer Institute*

Dr. Kowalski is Director, Biostatistics and Bioinformatics shared resource for the Winship Cancer Institute at Emory University. She holds a faculty appointment of Associate Professor in the Department of Biostatistics and Bioinformatics at the Rollins School of Public Health. Prior to her recent arrival at Emory, Dr. Kowalski was Associate Professor in the Division of Biostatistics and Bioinformatics at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins.

Dr. Kowalski 's current research interest is in the design and analysis of clinical trials to assess the use of cancer stem cell-based therapies in treating multiple myeloma and acute myeloid leukemia (AML) for which she holds an award from The Leukemia & Lymphomas Society. Dr. Kowalski's additional research interest is in nonparametric analyses of high-dimensional genetic and genomic data and their incorporation into trial designs and evaluation, such as needed for epigenetic-based therapies.

She co-authored a graduate textbook on U-Statistics and is co-editor of the book series, “Applied Bioinformatics and Biostatistics in Cancer Research.”

**Gregory Orloff, MD**  
*Virginia Cancer Specialists*

Dr. Orloff, a native of metropolitan Washington, DC, is a Phi Beta Kappa graduate of Grinnell College. He attended Yale Medical School where he graduated and was selected to the Alpha Omega Alpha honor society. He completed his medical internship, resident, and hematology/oncology fellowship at the Brigham Women’s Hospital and the Dana Farber Cancer Institute in Boston, Massachusetts. At the conclusion of his training, he joined the faculty in the Hematology/Oncology division at the Brigham Women’s Hospital at Harvard Medical School.

Dr. Orloff is a member of the American Society of Hematology, the American Society of Clinical Oncology, and the American Society of Bone Marrow Transplantation. He is Co-Director of the Bone Marrow Transplant Program in INOVA Fairfax Hospital.

## **BIOGRAPHIES – PARTICIPANTS (CONT)**

### **David Siegel, MD, PhD**

*John Theurer Cancer Center at  
Hackensack University School of Medicine*

Dr. Siegel, chief of the Division of Multiple Myeloma, is one of the nation's foremost authorities on multiple myeloma (MM). He has more than 25 years of significant clinical and research expertise in treating and managing MM.

Dr. Siegel received his medical degree from The New York University School of Medicine and a master's degree and doctorate in immunology from The New York University Graduate School of Arts and Sciences Sackler Institute of Basic Medical Sciences. He completed a residency in internal medicine at New York University/Bellevue Medical Center and a fellowship in hematology/oncology at Memorial Sloan-Kettering Cancer Center, in New York City. Prior to joining The John Theurer Cancer Center at Hackensack University in 2002, Dr. Siegel was on the faculty of Memorial Sloan-Kettering Cancer Center, The University of Arkansas Cancer Research Center, and Atlantic Health System's Stem Cell Transplantation Program.

Dr. Siegel has devoted most of his clinical and research career to the diagnosis, treatment, and management of MM. He is one of a handful of physicians in the United States who have such specialized expertise in caring for patients with this disease. He is one of 11 investigators nationwide who have brought the exciting new chemotherapeutic agent Velcade<sup>®</sup> to the treatment of multiple myeloma. He has also been involved in clinical trials for Revimid<sup>®</sup>, a new chemotherapeutic agent, and Xcytes, T cells that are produced to accelerate blood cell recovery after stem cell transplantation. Dr. Siegel's research has almost exclusively focused on multiple myeloma and has been published in many leading medical journals, including the *British Journal of Haematology*, *The New England Journal of Medicine*, *Blood*, and *Bone Marrow Transplant*. He is a member of the Multiple Myeloma Research Consortium (MMRC).

**BIOGRAPHIES – PARTICIPANTS (CONT)****Michael Tomasson, MD**  
*Washington University*

Dr. Tomasson is currently Associate Professor of Medicine and Genetics and Scientific Director for the Siteman Cancer Center Myeloma Program at Washington University, St. Louis. After completing his residency and internship in internal medicine at Stanford University Hospital, a fellowship in hematology/oncology at Massachusetts General Hospital, he was an Instructor of Medicine at Harvard Medical School.

Dr. Tomasson's research focuses on understanding the genetic basis of hematologic malignancies associated with characteristic chromosomal translocations. His lab has established mouse models of t(5;12) chronic myelomonocytic leukemia (CMML) to understand TEL-PDGFRB fusion protein, and t(8;21), AML1-ETO-induced acute myeloid leukemia (AML). He has established the important roles of *Stat5* and *Mcl1* in these diseases using reverse genetic approaches. Using array comparative genomic hybridization and high throughput resequencing from AML and multiple myeloma (MM) patients, he identified novel mutations. Genomic analysis of MM patient samples with del13 and t(4;14) identified a noncanonical role for RB which he uses to genetically model MM in mice.

As a practicing hematologist/oncologist who specializes in stem cell transplantation, Dr. Tomasson has participated in the development of numerous clinical trials and was part of the team of researchers that sequenced the first cancer genome in a patient with AML. As Scientific Director of the MGUS/Multiple Myeloma research program at Washington University School of Medicine, he established the MGUS/MM tissue bank of patient samples divided into tumor, associated stroma, and normal tissue, which is now one of the largest and most complete in the country. Using a custom made chromosome 4 tiling array to analyze tissue from MM patients with t(4;14), he uncovered a highly expressed snoRNA, ACA11, a novel candidate oncogene, at the t(4;14)-breakpoint. Dr. Tomasson has been an NIH-funded investigator for 13 years.

**BIOGRAPHIES – MMRF/C****Susan L. Kelley, MD***Multiple Myeloma Research Consortium*

Dr. Kelley is Chief Medical Officer at the Multiple Myeloma Research Consortium (MMRC) where she provides strategic medical leadership for the myeloma research and development activities supported by the MMRC and its sister organization, the MMRF.

Dr. Kelley has more than 20 years of experience in oncology clinical research and drug development within the pharmaceutical industry. Prior to joining the MMRC, Dr. Kelley served as Vice President and head of Global Oncology Clinical Development at Bayer Healthcare Pharmaceuticals, where she was responsible for the worldwide management of the oncology drug development portfolio and for management of Bayer's oncology drug development and franchise strategies. While at Bayer, she oversaw the successful advance of Nexavar<sup>®</sup> (sorafenib) through Phase III trials and the FDA approval process. Prior to her position at Bayer, Dr. Kelley held several leadership positions in Bristol-Myers Squibb Clinical Development, both in Oncology and Immunology. She joined the MMRC in 2008.

Dr. Kelley received her medical degree from Duke University School of Medicine. She completed certification in internal medicine at the University of Colorado followed by medical oncology training at the Dana-Farber Cancer Institute in Boston. Prior to joining the pharmaceutical industry, Dr. Kelley also conducted oncology clinical and laboratory research at Yale University School of Medicine.

**Joan Levy, PhD***Multiple Myeloma Research Foundation*

Dr. Levy is Associate Director of Research at the Multiple Myeloma Research Foundation (MMRF) where she is responsible for the planning and implementation of the MMRF's research agenda. She has more than 20 years of experience in oncology and osteoporosis research in both pharmaceutical and academic settings.

Prior to joining the MMRF, Dr. Levy was Technical Director at the Binding Site, where she supported the use of Freelite, a diagnostic assay for multiple myeloma. In addition, she worked at Bayer Pharmaceuticals Corporation in West Haven, CT, for nine years. In that capacity, she was engaged in target identification, compound validation, and project leadership in the fields of cancer and osteoporosis research. She has contributed to the delivery of novel drug candidates for clinical studies in each of these indications.

Dr. Levy earned her PhD at the University of Vermont and then completed two postdoctoral fellowships at the Rockefeller University and later at the State University of New York at Stony Brook. Her two academic appointments were at New York University Medical Center and Yale University, studying various aspects of cell signaling pathways involved in the pathogenesis of cancer and development of osteoporosis.

## **BIOGRAPHIES – MMRF/C (CONT)**

### **Louise M. Perkins, PhD**

*Multiple Myeloma Research Foundation*

Dr. Perkins is Chief Scientific Officer at the Multiple Myeloma Research Foundation (MMRF) where she is responsible for the development and execution of the MMRF's research strategy. Dr. Perkins brings more than 16 years of pharmaceutical research experience from two major companies to the MMRF.

Prior to joining the MMRF, she was Director of Cancer Research at Bayer Pharmaceuticals in West Haven, CT, where she contributed to advancing novel targeted therapies toward clinical study, including Nexavar<sup>®</sup> and other innovative signal transduction inhibitors. While at Bayer, she also served as the Director of Research Licensing and was responsible for oncology licensing activities in support of cancer research programs. Prior to joining Bayer, she led a cancer research group at the Schering-Plough Research Institute in Kenilworth, NJ. In this role, she participated in several early-stage research programs including novel target-finding research using human genomics data.

Dr. Perkins graduated from the University of Michigan with a PhD and MS in biological chemistry and conducted postdoctoral studies at Princeton University in the Department of Molecular Biology. She earned her Bachelor of Science in Zoology from the University of North Carolina at Chapel Hill.

**BIOGRAPHIES – MMRF/C PARTNERS****Cameron Dunnan***Quintiles Consulting*

Mr. Dunnan is a Principal Consultant and U.S. Due Diligence Practice Lead with Quintiles Consulting. He has more than 20 years of experience as a healthcare management consultant, biopharma business development strategy consultant, environmental engineering consultant, and quality compliance/regulatory specialist.

Mr. Dunnan's diverse range of healthcare strategy consulting experience includes strategic planning (corporate, franchise, brand), clinical development strategy and trial design, KOL research, epidemiological forecast modeling, financial valuation, and overall market opportunity assessment including product development and commercialization strategy for early-stage and marketed products spanning a number of therapeutic areas (cardiovascular [drugs and devices], respiratory, oncology, CNS/pain management, men's and women's health, metabolic disease/obesity, and natural products). Other recent content experience includes molecular/companion diagnostics and follow-on biologics.

Previous employment experience includes time with Johnson & Johnson (OMP & JJPRD), Bogart Delafield & Ferrier, Monitor Group/ISO Healthcare Consulting and Defined Healthcare Research.

Mr. Dunnan holds a Bachelor of Science degree in Biochemistry from Brown University and an MBA from Rutgers Business School.

**Chris Gabel, PhD***Quintiles Consulting*

Dr. Christian Gabel is a senior leader in Quintiles Consulting's Transformation practice. He has more than 14 years' experience developing and implementing transformative strategies, processes, and operations in drug development, registration, and commercialization for global clients in the pharmaceutical and biotechnology industries.

He is a practice area leader for the Clinical Transformation practice placing him at the focal point of Quintiles' Consulting, Clinical (CRO), and Commercial interface to plan, lead, and coordinate complex project efforts. He leads a team dedicated to improving how pharmaceutical and biotechnology companies operationalize their strategy in order to enhance all aspects of their clinical operations, including processes, organizational structure, and systems. He and his team have worked with large and small companies to drive strategies into concrete actions focused on efficiencies, compliance, and transformation of clinical development groups.

His personal consulting activities have focused on leading and managing large scale global projects and delivering results in the areas of clinical development process improvement, portfolio management and optimization, partnering and alliance management, as well as new product launch and marketing strategy development. His most recent clients include Novartis Oncology, sanofi-aventis, Élan, and Becton Dickinson.

Prior to joining Quintiles Consulting, Dr. Gabel was a senior leader in PRTM's Life Sciences Practice and was a senior member of Deloitte's Life Sciences Practice in the US and Europe

Dr. Gabel has a PhD in Molecular Biology from The Johns Hopkins University, an MBA from Carnegie Mellon University, and a BS in Biochemistry from the University of Rochester.

**BIOGRAPHIES – MMRF/C PARTNERS (CONT)****John McCormick***Quintiles Consulting*

Mr. McCormick possesses over 24 years working in Clinical Research with the last 10 years in Program/Project Management leading large global/multi-national studies across Western/Eastern Europe, South Africa, Australia, Asia, South America, and the United States. He has significant experience working in cardiology, respiratory, oncology, endocrinology, and CNS and has worked in dermatology, rheumatology, Men's and Women's Health, and urology. He has been responsible for the Project Management of a number of studies ranging from Phase I–IV. He has managed Phase III multi-national trials across 34 countries across 400 sites, and including over 15,000 patients. Responsibilities have spanned the full duration of studies, from start-up to project closeout and review.

Mr. McCormick was recently the Program Director for an IV formulation of a unique cardiovascular agent and was responsible for the oversight of the entire lifecycle of the product from clinical, manufacturing, supply, medical writing, and regulatory compliance.

Mr. McCormick played an integral role in the development of separate business units specializing in Late Phase Research at two global CROs. He was the Executive Director/Director of Operations in Late Phase at both organizations.

His current responsibilities include overseeing the global operations of Late Phase Project Management at Quintiles. He is also responsible for the overall Program Management of the Quintiles/Cerner Partnership in Late Phase. Other responsibilities include liaising with the customer and third party contractors, as well the co-ordination and management of the following service lines: Regulatory Affairs, Study Drug Management, Safety Surveillance & Reporting, Clinical Monitoring/Site Management, Data Management, Biostatistics, and Medical Writing.

**Mary Seate***Quintiles Consulting*

Ms. Seate has been with Quintiles over four years. Located in the Quintiles Research Triangle Park (Q RTP), North Carolina office, Ms. Seate currently serves as a Senior Project Manager within the Late Phase Project Management group of Global Project Management where she is responsible for the project management of various late phase and observational studies.

Ms. Seate has more than 11 years of CRO/pharma experience including roles in data management, clinical, and project management. She has extensive Phase I–IIIb clinical trial management experience working in various therapeutic areas.

She graduated from North Carolina State University (NCSU) with a degree in Zoology/Medical Technology and later returned to NCSU to receive a certificate in Computer Programming. Her career in clinical research began with Clintrials in 1997 where she spent over nine years in data management focusing on oncology trials. Her career continued at Abraxis Bioscience where she served as Director of Clinical Data Management. After two years, Ms. Seate made the transition to a clinical role as Clinical Research Associate monitoring oncology studies.

## **BIOGRAPHIES – MMRF/C PARTNERS (CONT)**

### **Arthur Sytkowski, MD**

*Quintiles Consulting*

Dr. Sytkowski is Executive Director in the Hematology and Oncology Therapeutic Delivery Unit of Quintiles. He earned his BS degree in Biology/Philosophy *summa cum laude* and his MS degree in Physiology (Endocrinology) from Marquette University. He earned his MD degree *summa cum laude* from the Medical College of Wisconsin. Dr. Sytkowski completed his residency in Internal Medicine at Peter Bent Brigham Hospital (now Brigham and Women's Hospital), Harvard Medical School, and fellowships in Pharmacology/Toxicology at the NIH and in Biological Chemistry at the Biophysics Research Laboratory, Harvard Medical School. He then completed a Clinical Fellowship in Hematology and Oncology at the Children's Hospital and the Dana-Farber Cancer Institute.

Dr. Sytkowski carried out research and practiced hematology and oncology at Boston Children's Hospital and the Dana Farber during which time he held the appointments of Assistant/Associate Professor of Pediatrics at Harvard Medical School and was a member of the Committee of Professors. He later was recruited to the Beth Israel Deaconess Medical Center in Boston and is currently Associate Professor of Medicine at Harvard.

Dr. Sytkowski has had a broad range of experience in drug research and development (Phases 1–4) as an academican, physician-scientist, director of research and development, clinical research investigator, attending physician, consultant, and program administrator in hematology/oncology, including international experience with numerous biotech and pharma companies in preclinical and clinical drug development and technology evaluation for investment purposes. He trained 42 MD and PhD post-doctoral fellows in his research laboratory, virtually all of whom have gone on to highly successful careers in industry or academia.

He is a member/fellow/officer in numerous medical, scientific and professional societies and has received several awards and honors. He has authored over 100 original scientific publications, patents, monographs, book chapters and one book. He has served as a consultant to many pharmaceutical and biotech companies in the United States, Europe, South America, Asia, and South Africa. Dr. Sytkowski has been with Quintiles since February 2008.

## PARTICIPANTS

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