

## Model-Informed Drug Development in Oncology

February 1, 2018

### SPEAKER BIO

#### Workshop Co-chairs

##### **Amy E. McKee, M.D.**

##### **Deputy Director (acting), Oncology Center of Excellence, and Supervisory Associate Director, Office of Hematology and Oncology Products (OHOP), FDA**

Dr. McKee is the Deputy Director (acting) for the Oncology Center of Excellence as well as Supervisory Associate Director in the Office of Hematology and Oncology Products (OHOP) of the Center for Drug Evaluation and Research, United States Food and Drug Administration. Dr. McKee received her B.A. from Middlebury College, and before obtaining her medical degree at Tulane University School of Medicine, Dr. McKee was a reporter for Elsevier's medical industry trade journal "The Pink Sheet." She completed her pediatric training at the Floating Hospital for Children/New England Medical Center and her pediatric hematology/oncology training at the combined Johns Hopkins University/National Cancer Institute fellowship program. Since joining the FDA, she has reviewed numerous new molecular entities for marketing approval in oncology; authored several manuscripts on new approvals, on targeted therapy drug development and on clinical trial endpoints for regulatory applications; and chaired workshops on dose-finding in oncology and accelerating new product development for ovarian cancer.

##### **Yaning Wang, Ph.D.**

##### **Director, Division of Pharmacometrics (DPM), Office of Clinical Pharmacology (OCP), OTS, CDER, FDA**

Dr. Yaning Wang is currently the Director of the Division of Pharmacometrics in the Office of Clinical Pharmacology at FDA. Before joining FDA, Dr. Wang received his Ph.D. in Pharmaceutics and master's degree in Statistics from the University of Florida from 1999 to 2003. He also obtained a master's degree in Biochemistry (1999) from National Doping Control Center and a bachelor's degree in Pharmacy (1996) from Peking University in China. Dr. Wang oversees reviews, research projects, and policy development within the Division of Pharmacometrics for all disease areas. During his fifteen years of service at FDA, Dr. Wang received numerous awards, including Award of Merit and FDA Outstanding Service Award. Dr. Wang is an Adjunct Professor in the Department of Pharmaceutics at the University of Florida and an invited lecturer in the College of Engineering and College of Pharmacy at the University of Michigan. Dr. Wang is a regulatory expert lecturer for American Course on Drug Development and Regulatory Sciences (ACDRS) organized by University of California at San Francisco (UCSF), European Course in Pharmaceutical Medicine (ECPM) organized by University of Basel, and Chinese Course on Drug Development and Regulatory Sciences

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(CCDRS) organized by Peking University Clinical Research Institute in collaboration with University of Basel and UCSF. He served as a board member of the International Society of Pharmacometrics. He is a member of the Advisory Committee for Chinese Pharmacometrics Society and a member of the Editorial Advisory Board for the Journal of Pharmacokinetics and Pharmacodynamics.

### **René Bruno, Ph.D.**

#### **Past-President, ISoP**

#### **Staff Scientist, Clinical Pharmacology, Roche/Genentech**

René Bruno provides scientific leadership in the development and application of Modeling and Simulation (M&S) in drug development, with a special focus in oncology and immuno-oncology supporting various early and late stage projects. René has more than 30 years of experience in academia, industry, and consulting business, including University of Marseilles (Assistant Professor 1982-85), Syntex (1985-87), Rhone-Poulenc Rorer (1987-2000), and Genentech (2000-2003 as Sr. Scientist, Head of Pharmacometrics). In the most recent 13 years before coming back to Genentech in June 2016, René was Managing Director in Pharsight/Certara Consulting Services where he provided Modeling and Simulation (M&S) consultation for small biotech to leading pharmaceutical companies worldwide. René specific research interest has been in oncology tumor growth inhibition modeling, including linking tumor response to outcomes data such as Overall Survival, and application of these models to trial design and development decisions. He has published 70+ peer-reviewed research articles, 16 invited book chapters, reviews, and commentaries, and delivered 50+ invited lectures at global scientific conferences and universities. René is one of the founding members of the Population Approach Group in Europe (PAGE) and hosted the 1st meeting in 1993 in Paris. Rene served as the president of the International Society of Pharmacometrics (ISoP) (2017).

### **Jin Y. Jin, Ph.D.**

#### **President, ISoP**

#### **Director and Principal Scientist, Global Head of M&S, Clinical Pharmacology, Genentech**

Dr. Jin Yan Jin is Director and Principal Scientist, Global Head of Modeling and Simulation (M&S) in Clinical Pharmacology at Genentech, and oversees clinical M&S and data programming activities for all molecule types in various therapeutic areas. She also acts as Group Leader for OMNI Clin Pharm Group 3 – Neuroscience and oversees overall clinical pharmacology support for all neuroscience molecules in Genentech portfolio. She has been actively involved in M&S during development and/or registration for many molecules, including Atezolizumab, Avastin, Cobimetinib, Herceptin SC, Pertuzumab, T-DM1, Venetoclax, Vismodegib, and Xolair. Before joining Genentech in 2009, she worked at Eli Lilly in metabolism and neuroscience areas after Ph.D. and post-doc in Pharmaceutical Sciences from the State University of New York at Buffalo. Dr. Jin is a committed member of the scientific community

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with active presentations/publications. She serves on the Board of Directors for International Society of Pharmacometrics (ISoP) and is currently the President for ISoP. She is also on the Editorial Board for Clinical Pharmacology and Therapeutics: Pharmacometrics and System Pharmacology (CPT:PSP), and involved in various Task Forces and activities for American Society for Clinical Pharmacology and Therapeutics (ASCPT). She chaired the 2015 American Conference on Pharmacometrics annual meeting (ACoP6). Dr. Jin has over 50 publications, gave over 25 invited talks, and moderated many scientific workshops and sessions.

### Workshop Speakers and Panelists

#### **Issam Zineh, Pharm.D., MPH**

##### **Director, Office of Clinical Pharmacology (OCP), OTS, CDER, FDA**

Dr Zineh is Director of the Office of Clinical Pharmacology (OCP) at the US Food and Drug Administration (FDA). He has held various positions at FDA including Associate Director for Genomics (2008-2012), Co-Director of the CDER Biomarker Qualification Program (2009-2015) and voting member of the CDER Medical Policy Council (2016-present). He is an experienced pharmacist and applied clinical pharmacologist who was formerly on the faculty of the University of Florida (UF) Colleges of Pharmacy and Medicine and Associate Director of the UF Center for Pharmacogenomics. received his PharmD from Northeastern University and completed his residency at Duke University Medical Center. He completed a fellowship in cardiovascular pharmacogenomics at UF where he also obtained his MPH in Health Policy and Management. He is a recognized expert in the field of drug development and evaluation, clinical pharmacology, Pharmacotherapy, and precision medicine. As Director of OCP, Dr. Zineh leads a staff of approximately 230 regulatory, research, program/project management, and administrative staff in FDA's efforts to enhance drug development and promote regulatory innovation through clinical pharmacology and experimental medicine.

#### **Janet Woodcock, M.D.**

##### **Director, Center for Drug Evaluation and Research (CDER), FDA**

Dr. Woodcock held various positions within the Office of the Commissioner, FDA from October 2003- April 1, 2008 as Deputy Commissioner and Chief Medical Officer, Deputy Commissioner for Operations and Chief Operating Officer and Director, Critical Path Programs. She oversaw scientific and medical regulatory operations for FDA. Dr. Woodcock served as Director, Center for Drug Evaluation and Research at FDA 1994-2005. She previously served in other positions at FDA including Director, Office of Therapeutics Research and Review and Acting Deputy Director, Center for Biologics Evaluation and Research. Dr. Woodcock received her M.D. from Northwestern Medical School, and completed further training and held teaching appointments at the Pennsylvania State University and the University of California in San Francisco. She joined FDA in 1986.

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### **Sergey Aksenov, Ph.D.**

#### **Pharmacometrics Lead, Quantitative Clinical Pharmacology, AstraZeneca**

Sergey Aksenov is the Pharmacometrics Lead in the Quantitative Clinical Pharmacology department at AstraZeneca. Trained as a physicist he had worked at a biosimulation company GNS Healthcare and in the Modeling and Simulation department at Novartis before joining AstraZeneca. While at GNS Healthcare he developed modeling and simulation platforms using Bayesian networks for analysis of high-dimensional proteomic, genomic and clinical data for drug target qualification, and mechanistic dynamical models of protein interaction networks driving cancer development. While at Novartis and AstraZeneca he has developed pharmacokinetic, pharmacodynamic, physiological, mechanistic and statistical models supporting clinical trial design and interpretation from early phase trials through NDA submission and drug label negotiation. In his current role at AstraZeneca he is leading the pharmacometrics scientists, providing technical guidance in oncology, respiratory and cardiovascular/metabolic disease modeling, and leading the pharmacometrics vision and strategy to best incorporate pharmacometrics science into drug development.

### **Armin Sepp, Ph.D.**

#### **Scientific Leader and GSK Associate Fellow, Systems Modeling and Translational Biology, GlaxoSmithKline**

Armin Sepp is Scientific Leader and GSK Associate Fellow at the Systems Modeling and Translational Biology group of GlaxoSmithKline where he is providing early stage project support for biotherapeutic projects covering mAbs, antibody fragments as well as cell and gene therapy products. His post-doctoral training in protein engineering and in vitro evolution at the MRC Immunochemistry Unit in Oxford and MRC Laboratory of Molecular Biology in Cambridge was followed by application of the experience gained in the field of antibody engineering as Senior Scientific Investigator at Domantis Ltd in Cambridge. This start-up company focused on the development of human heavy and light chain antibody variable domains (dAbs) as a novel therapeutic platform and was acquired by GlaxoSmithKline in 2007. From there on, the need for improved predictive mechanistic understanding of the tissue distribution, penetration and elimination properties of these novel therapeutics, as well as biologics in general, led him to modeling and simulation, with focus on cross-platform/cross-species physiologically based pharmacokinetics of therapeutic proteins. Armin has contributed to 15 patents and authored 19 papers.

### **Dean Bottino, Ph.D.**

#### **Senior Scientific Director, Quantitative Clinical Pharmacology, Takeda**

Dean Bottino received his PhD in Applied Mathematics from Tulane University in 1996. His academic work at Tulane, and subsequently at University of Utah and UC Berkeley, consisted of spatiotemporal simulations of eukaryotic cell motility and chemotaxis. Dr. Bottino then moved into industry, joining Physiome Sciences in 2001, co-founding the BioAnalytics Group LLC in

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2003, then moving on to Novartis in 2005, Roche in 2011 and Millennium (Takeda) in 2013, where he is currently senior scientific director in the quantitative clinical pharmacology group. He has specialized in preclinical and clinical modeling and simulation in oncology since 2005.

### **Haleh Saber, Ph.D.**

#### **Deputy Director, Division of Hematology Oncology Toxicology (DHOT), OHOP, CDER, FDA**

Dr. Saber is currently the Deputy Director in the Division of Hematology Oncology Toxicology (DHOT). In this role, she provides leadership for day-to-day activities, coordinates scientific research, and participates in oncology guidance development. Dr. Saber has extensive industry and regulatory experience. She served as a Subject Matter Expert assisting pharmaceutical companies worldwide in nonclinical drug development and served many roles at the FDA over 12 years, starting as a primary reviewer before becoming a Supervisory Pharmacologist in DHOT. Dr. Saber is recognized nationally and internationally for her efforts in establishing acceptable approaches in first-in-human dose selection for new classes of products. She has been the recipient of multiple CDER awards. Dr. Saber received her PhD in Biochemistry from Lehigh University and conducted her post-doctoral studies at Fox Chase Cancer Center.

### **Sandeep Dutta, Ph.D.**

#### **Executive Director, Global Head, Clinical Pharmacology, Modeling and Simulations, Amgen**

Dr. Sandeep Dutta is Executive Director and Global Head of Clinical Pharmacology, Modeling and Simulations, Amgen. Dr. Dutta received his Ph.D. from the State University of New York at Buffalo, NY, USA and has two decades of broad drug development, translational sciences and management experience. Dr. Dutta has been a primary contributor to 10 (s)NDA/MAA/JNDA approvals and over 75 INDs. Dr. Dutta has published over 250 peer-reviewed articles and abstracts, received 14 patents, is member of multiple PhRMA/Academia/Regulatory initiatives/working groups, been invited as a speaker to several conferences, has served as Workshop/Symposium Chair and serves on Editorial Boards of multiple journals. His fields of expertise include theoretical and clinical PK/PD, clinical pharmacology, exposure-response modeling & simulation of clinical trial outcomes, Phase 2/POC dose selection, model based meta-analyses, animal-to-human scaling, FIH & Phase 1 study design/execution/analyses, drug-drug interactions and development of IVIVC models for modified-release dosage forms.

### **Stuart Bailey, Ph.D.**

#### **VP, Biostatistics and Pharmacometrics, Novartis**

Stuart leads the Analytics team supporting Oncology and Discovery Research and has spent 15 years developing an adaptive dose finding environment to support more quantitative early development and early decision, including novel designs for multi-drug combinations, pediatrics studies and pan-Asian escalation studies. Stuart holds a Doctorate from Sussex University, U.K.

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and his more recent research areas focus on evolutionary dynamics of tumors and the application of machine learning algorithms to multisource data (e.g., clinical, imaging, RWE) in support of better disease models to contextualize drug activity.

### **Tito Fojo, M.D., Ph.D.**

#### **Professor of Medicine, Columbia University**

Dr. Fojo received his MD and PhD from the University of Miami and completed internal medicine training at Washington University School of Medicine/Barnes Hospital. He joined the National Cancer Institute in 1982 as a Clinical Associate in the Medicine Branch and after training with Drs. Ira Pastan and Michael Gottesman, became a Principal Investigator in the Medicine Branch of the National Cancer Institute. Dr. Fojo has expertise in the management of patients with adrenocortical cancer, malignant pheochromocytoma and other neuroendocrine malignancies, and thyroid cancer. These cancers also comprise areas of very active basic science interest given their unique properties and the possibilities to target such cancers more precisely. The ultimate goal is to develop novel therapies for these often very refractory cancers so that there will be additional options available for treatment for patients with these cancers. Ongoing laboratory efforts are focused on developing such novel therapies to treat patients with adrenal cancer, pheochromocytoma and a spectrum of neuroendocrine tumors. In the laboratory Dr. Fojo has also worked to understand the molecular basis of drug resistance, and was involved in the original work relating to several ABC transporters. Additionally, his laboratory originally identified rearrangements involving the MDR-1 gene as a novel mechanism of drug resistance in several cancers, a molecular event recently demonstrated as very important in ovarian cancer. He has also been very involved in research on microtubule-targeting agents, helping to establish as a novel paradigm the interference with microtubule trafficking, rather than mitosis, for the mechanism of action for these important drugs. In addition to his clinical expertise Dr. Fojo has been very interested in the design, conduct and interpretation of oncology clinical trials and in collaboration with Wilfred Stein, PhD and Susan Bates, MD has helped to pioneer a novel method of analysis that dissects rates of tumor growth and regression as concurrent events. Related to this he has also written extensively about the cost of cancer therapeutics, the magnitude of the problem and how this might be addressed. Dr. Fojo served as Program Director for the Medical Oncology Fellowship Program at the National Cancer Institute, the largest fellowship program in the NIH and one of the largest medical oncology programs in the United States. Over the years Dr. Fojo has helped to train more than 350 medical oncologists.

### **Jérémie Guedj, Ph.D.**

#### **Research Scientist, French National Institute of Health and Medical Research (INSERM)**

Jérémie Guedj is a researcher at the French National Institute of Health and Medical Research (INSERM) since 2012. My main research interest is in pharmacometrics in infectious diseases, i.e., the development of mathematical and statistical models to optimize the response to antiviral

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treatment. Together with Alan Perelson I have been involved in the last 10 years in the development of mechanistic models for new antiviral agents against HIV, Hepatitis C virus and emerging infections such as Ebola virus. I started to work on joint models in the context of HIV to evaluate the role of CD4 as a surrogate marker of treatment efficacy and the use of mechanistic model to predict time to disease progression and AIDS. In 2014, we initiated together with France Mentré and Christine Veyrat-Follet at Sanofi a collaboration on joint model and PSA kinetics, the goal being to assess the relationship between PSA and survival in metastatic patients and to improve the early prediction of disease progression using a semi-mechanistic characterization of PSA kinetics.

### **Michael Maitland, M.D., Ph.D.**

#### **Director, Therapeutics, Inova Center for Personalized Health**

Dr. Michael Maitland is a physician-scientist who conducts patient-oriented research in biomarker development and clinical pharmacology of cancer therapeutics. He is a practicing medical oncologist who provides care for patients with advanced metastatic disease and serves as Principal Investigator on Industry and US National Cancer Institute-sponsored clinical trials in early therapeutics. He is currently co-Principal Investigator on a NCI RO1 Academic-Industry Partnership grant entitled- "Computational modeling of tumor burden by CT to advance cancer therapeutics." After completing his training and serving on the faculty at University of Chicago for more than a decade, Dr. Maitland moved nearby to Northern Virginia in 2016 to take a leadership role in the Inova Health System. The System treats more than 2 million people every year. There he serves as Director of Therapeutics for the Inova Center for Personalized Health and he treats patients in the System's Schar Cancer Institute. The flagship Inova Fairfax Hospital has more than 800 beds and is a main teaching site for the Virginia Commonwealth University where Dr. Maitland is a Professor of Internal Medicine.

### **David Turner, Ph.D.**

#### **Associate Principal Scientist, Quantitative Pharmacology and Pharmacometrics, Merck**

David joined Merck in 2014 and has contributed to PK and exposure-response analyses justifying Keytruda dose across several global filings. In 2016, David stepped in as the primary PPDM-QP2 functional representative on the Keytruda NSCLC PDT, delivering critical strategy decisions and M&S support for approval of the Keytruda fixed dose. In addition to these activities, David has co-authored 30+ scientific publications in the fields of drug delivery and PK/PD analysis. David earned his undergraduate degree in chemistry at the University of Georgia and Ph.D. in Pharmaceutical Sciences from Mercer University where he focused on targeted drug delivery. He joined Merck following completion of a three-year postdoctoral fellowship at St Jude Children's Research Hospital where he specialized in bioanalytical methods and population PK/PD analyses to establish pediatric dosing guidelines for chemotherapy in infants and young children.

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### **Yanan Zheng, Ph.D.**

#### **Principal Scientist, Clinical Pharmacology & DMPK, MedImmune**

Yanan Zheng is a Principal Scientist in Clinical Pharmacology & DMPK at MedImmune. Previously she worked at Genentech as a Scientist in Clinical Pharmacology. Prior to joining Genentech, she worked at Entelos as a Biosystems Engineer working on large-scale computer-based disease models. Yanan earned her Ph.D. in Biomedical Engineering from Purdue University.

### **Amit Roy, Ph.D.**

#### **Group Director, Clinical Pharmacology & Pharmacometrics, Bristol-Myers Squibb**

Amit Roy is currently Group Director in the department of Clinical Pharmacology & Pharmacometrics at BMS, where he serves as the Head of Pharmacometrics for Oncology. Amit received his undergraduate degree in Chemical Engineering from the University of Michigan, in Ann Arbor, and his Ph.D. in Chemical & Biochemical Engineering from Rutgers University in 1997, following which he was Assistant Professor in the Department of Community Medicine at the University of Medicine and Dentistry of New Jersey. Prior to joining BMS in Sept 2004, Amit worked as a clinical pharmacologist at Vertex Pharmaceuticals, in Cambridge, MA, where he supported the development of several immunology compounds.

### **Jingwen (Jenny) Zheng, Ph.D.**

#### **Director, Global Pharmacometric group, Pfizer**

Dr. Jenny Zheng is currently a pharmacometric scientist in Global Pharmacometric group, Pfizer Inc. She has 21 years of drug development experience, 10 years in FDA and 11 years in industry, working in both clinical pharmacology and pharmacometric areas. Dr. Zheng received the PhD in University of Southern California and had post-doctoral training in pharmacokinetic and pharmacodynamics area in University of California, San Francisco. After her post-doctoral training, she joined the Office of Clinical Pharmacology (OCP) in the Food and Drug Administration (FDA). In FDA, she was a clinical pharmacology reviewer and transferred to the pharmacometric group when the pharmacometric group was first created in FDA. She contributed to the numerous reviews of INDs and NDA submissions. She conducted various PK/PD analyses to support the regulatory decisions. She supported the early end of Phase 2 A programs and represented FDA to present her PK/PD analysis in an advisory committee meeting. After 10 years in FDA, Dr. Zheng joined the industry working on both small and large molecules in various therapeutic areas, e.g. anti-infective, antiviral, neuroscience, bone, and oncology areas.

### **Nam Atiqur Rahman, Ph.D.**

#### **Director, Division of Clinical Pharmacology V, Office of Clinical Pharmacology (OCP), OTS, CDER, FDA**

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Nam Atiqur Rahman, PhD, is the Director of the Division of Clinical Pharmacology V within the Office of Clinical Pharmacology (OCP), Center for Drug Evaluation and Research, U.S. Food and Drug Administration (U.S. FDA). The Division consists of 26 clinical pharmacology reviewers who are involved in pharmaceutical product development, product review, and approval. The Division supports evaluation of Hematology/Oncology and Medical Imaging products. Prior to joining the FDA, Dr. Rahman completed post-doctoral training at the St.-Jude Children's Research Hospital, Memphis, Tennessee in Molecular Pharmacology and Pharmacogenomics. Dr. Rahman's current interest includes dose optimization in oncology drug development, application of modeling and simulation in oncology drugs and biologics development, and application of pharmacogenomics to promote personalized medicine for patients. He leads and supports the review staff that addresses various scientific challenges in drug development and approval, and interacts with pharmaceuticals to promote and facilitate oncology drug development from Clinical Pharmacology perspectives. Dr. Rahman has been involved with the biosimilar program and a member of various committees and working groups at the Center level dealing with the FDA biosimilar program. Dr. Rahman is a member of the Biologics Oversight Board within OCP. The board provides recommendation to the review teams on Biocomparability and Biosimilarity related clinical pharmacology issues. Dr. Rahman has written four book chapters, over 35 articles in peer reviewed journals, and made numerous presentations in various national and international scientific forums.

### **Jerry Yu, Ph.D.**

#### **Team Leader, Division of Pharmacometrics (DPM), Office of Clinical Pharmacology (OCP), OTS, CDER, FDA**

Dr. Yu got his BS and MS in Chemistry from University of Science and Technology of China in 2006. He then earned a PhD in Pharmaceutical Chemistry and MA in Statistics from University of Michigan, Ann Arbor in 2011. He currently is the team leader in Division of Pharmacometrics at US FDA. He has extensive experience in applying clinical pharmacology and pharmacometrics principles to the regulatory review and development of drug products in number of therapeutic areas including oncology, hematology, rheumatology, anti-infective, endocrine disorder, and pulmonary disease. He has a record of leading a number of regulatory science products, including several funded by Regulatory Science Research (RSR) and Office of Women's Health (OWH) grants, and mentoring others.

### **Kellie Turner-Jones, Ph.D.**

#### **Senior Research Scientist, Global PK/PD & Pharmacometrics, Eli Lilly and Company**

Kellie Turner is a Senior Research Scientist at Eli Lilly, where she is the PK/PD project leader for abemaciclib. She completed her pharmacy degree in 2002 and her PhD in 2007 at the University of Tennessee Health Science Center and St. Jude Children's Research Hospital. From 2007-2009 she was a postdoctoral fellow at the Northern Institute for Cancer Research,

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Newcastle University (UK). She has more than 8 years of experience at Eli Lilly using modelling and simulation to inform oncology drug development from candidate identification through regulatory submission and approval, with a focus on dose justification based on exposure-response analysis and for drug interactions and special populations. Her research has been published in numerous peer-reviewed journals, and she received the John L. Emmerson Award in 2017.

### **Chao Liu, Ph.D.**

#### **Team Leader, Division of Pharmacometrics (DPM), Office of Clinical Pharmacology (OCP), OTS, CDER, FDA**

Dr. Chao Liu is currently a team leader at Division of Pharmacometrics, Office of Clinical Pharmacology at the US FDA. Prior to becoming a team leader at OCP, he was a pharmacometrics reviewer at FDA. Dr. Liu received his Ph.D. degree in Immunology and Microbiology from the University of Florida, Gainesville in 2014. His Ph.D. study focused on immunological mechanisms in autoimmune disease. During that period, Dr. Liu also earned a Master's degree in Statistics. Dr. Liu earned a B.S in biological science from Nankai University in China. In his current role at the FDA, Dr. Liu works in the areas of hematology-oncology, cardiovascular and renal products, as well as antimicrobial/antiviral products. His current interest is focused on applying pharmacometrics for optimizing the drug development (such as dose selection and study design) and description of disease progression in oncology, as well as other therapeutic areas.

### **Daniele Ouellet, Ph.D.**

#### **Senior Director and TA-Group Leader, Global Clinical Pharmacology, Janssen Research & Development**

Daniele is currently Senior Director and Therapeutic Area (TA)-Group Leader, Global Clinical Pharmacology (GCP) at Janssen Pharmaceutical in Spring House, PA. Prior to joining Janssen, Daniele was Senior Director in the Clinical Pharmacology Modeling & Simulation (CPMS) group at GlaxoSmithKline, and TA-Head of the CPMS-Oncology group in Research Triangle Park, NC. Daniele has been working in the pharmaceutical industry for more than 20 years, joining Janssen in 2015. Prior to joining Janssen, Daniele worked at GSK, Pfizer (formerly Parke-Davis, Ann Arbor, MI), as a consultant at Phoenix Int (Montreal, Canada), and at Abbott Labs (Abbott Park, IL). Daniele is responsible for implementing model based drug development principles in the development of the oncology solid tumor portfolio. She is responsible for the clinical pharmacology and pharmacometric strategies within clinical development plans and provides oversight for regulatory submissions. Her area of expertise includes applying exposure-response analysis and clinical trial simulation for dose selection, evaluation of study design options, and quantitative decision making. Daniele served as a member of the International Society of Pharmacometrics (ISOP) Board of Directors and conference chair of the annual ACoP meeting in 2016, has published 50 original articles, multiple abstracts, and is a peer

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reviewer for different scientific journals. Daniele graduated with a Bachelor in Pharmacy from the University of Montreal in Canada and with a MS (Drug Development) and PhD (Pharmaceutical Sciences) from the University of North Carolina at Chapel Hill.

### **Lei Nie, Ph.D.**

#### **Team Leader, Division of Biometrics V, Office of Biostatistics (OB), OTS, CDER, FDA**

Lei Nie is a lead mathematical statistician of the Division of Biometrics V in the Office of Biostatistics (OB), Office of Translational Sciences (OTS), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). He has supported the anti-viral products from 2007-2013 and hematology products since 2013. Dr. Nie received his Ph.D. in Statistics from the University of Illinois at Chicago. Prior to coming to FDA, Dr. Nie was a faculty member in the University of Maryland Baltimore country from 2002-2005 and Georgetown University from 2005-2007. He has authored/coauthored 90 peer reviewed journal articles.

### **Patricia Keegan, M.D.**

#### **Division Director, Division of Oncology Products 2 (DOP2), OHOP, CDER, FDA**

Dr. Keegan is the Director of the Division of Oncology Products 2 (DOP2) in the Office of Hematology and Oncology Drug Products, in the Center for Drugs Evaluation and Review (CDER) at FDA. DOP2 provides regulatory oversight of pre- and post-market clinical development of investigational drugs and biologic products for the treatment of head and neck, lung, gastrointestinal, CNS, sarcomas, melanomas, pediatric and rare cancers. Dr. Keegan joined the FDA in 1990 in the Center for Biologics Evaluation and Review (CBER) and served as Branch Chief for the Oncology Branch within Division of Clinical Trials Design and Analysis (DCTDA) in the Office of Therapeutics Research and Review from 1993-1998 and as Deputy Division Director, DCTDA from 1998-2003. From 2003 to 2011, she served as the Director of the Division of Therapeutic Biologic Oncology Products in CDER with regulatory oversight of pre- and post-market clinical development of well-characterized biologic products for cancer. Prior to joining FDA, Dr. Keegan was a clinical assistant professor at the University of North Carolina at Chapel Hill (UNC-CH) and at Roswell Park Cancer Center. She received her medical degree at the Loyola University, Maywood IL, where she also completed an Internal Medicine residency and completed a fellowship in Medical Oncology at Roswell Park Cancer Center.