

## Meet the Network and Community Leadership

### Network: Development, Regulatory, and Outcomes (DRO)



**Network Chair:**  
**Lei Zhang, PhD**

Dr. Zhang is Senior Advisor for Regulatory Programs and Policy in the Office of Clinical Pharmacology, Office of Translational Sciences, the Center for Drug Evaluation and Research, the U.S. Food and Drug Administration (OCP/OTS/CDER/FDA). She is an accomplished professional with more than 17 years of combined experiences in the areas of drug research, development and regulatory review and approval. She received her Ph.D. in Biopharmaceutical Sciences from the University of California, San Francisco (UCSF). She worked at Bristol-Meyers Squibb Company as a Research Investigator and Preclinical Candidate Optimization Team Leader before she joined the FDA in 2002. Dr. Zhang is a member of several FDA working groups for regulatory guidance development and revision including guidances on drug interactions, pharmacokinetics studies in renal impairment patients, clinical pharmacogenomics, clinical pharmacology data to support biosimilarity determination, and clinical pharmacology labeling. Her research focuses on the science-based regulatory decision-making and applying clinical pharmacology principles through drug development and regulatory approval, in particular drug interactions, drug transporters, pharmacogenomics, specific populations, and PBPK modeling. Dr. Zhang is a member of the International Transporter Consortium (ITC) that published a transporter whitepaper in 2010 and several whitepapers/position papers in 2013. Dr. Zhang is a member of ASCPT, AAPS and ISSX. She serves/served on the ASCPT Scientific Program Committee (chaired the Scientific Program Committee for the 2015 ASCPT Annual Meeting), the Education Committee, the Scientific Award Nomination Task Force, and the CPT Editorial Board. She is also a member of the ISSX Regulatory Affairs Committee. Dr. Zhang was named AAPS Fellow in 2013. She is an Associate Adjunct Professor in the Department of Bioengineering and Therapeutic Sciences, UCSF Schools of Pharmacy and Medicine. Dr. Zhang has authored and co-authored numerous papers, book chapters, abstracts, and invited presentations in the areas of clinical pharmacology. She is Chair of the newly formed Development, Regulatory and Outcomes (DRO) Network within ASCPT.