## Meet the Network and Community Leadership Network: Development, Regulatory, & Outcomes (DRO) Community: Early Development & Drug Safety (EDDS)



Community Vice Chair: Sandeep Dutta, PhD 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 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 metaanalyses, animal-to-human scaling, FIH & Phase 1 study design/execution/analyses, drug-drug interactions and development of IVIVC models for modified-release dosage forms. Dr. Dutta has been a primary contributor to 10 (s)NDA/MAA/JNDA approvals and over 75 INDs, and has mentored many scientists and leaders in Clinical Pharmacology, PKPD and Pharmacometrics. Some of his most significant contributions include: (1) quantitative determination of optimal regimen and dose to drive critical decision to shorten duration of first interferon-free HCV treatment from 48 to 12 weeks for the approved 3D combination (Viekira Pak/Technivie), and (2) as primary Clinical Pharmacologist for multiple approvals of Depakote family of products. Previously at AbbVie, in addition to leading multiple therapeutic areas in Clinical Pharmacology, he was instrumental in guiding the vision, strategy and tactical execution plan for expansion of the Pharmacogenetics/genomics Department and the creation of the Bioinformatics group.