I am currently Senior Director, Clinical Pharmacology, at Pfizer Inc. I have more than 20 years of experience in the application of quantitative clinical pharmacology and pharmacometric principles for drug development and approval. I am specifically interested in linking the discipline of Pharmacometrics to strategic aspects of drug development and impacting drug development decisions. I obtained my doctoral degree in Pharmaceutical Sciences from the University of Tennessee Health Science Center, Memphis, TN, and completed post-doctoral training in Pharmacometrics at the University of Nebraska Medical Center, Omaha, NE, prior to joining the Clinical Pharmacology group at Pfizer. I have published more than 40 manuscripts and conference abstracts, and have been an invited speaker or moderator at FDA and scientific conferences such as ACoP, AAPS, DIA, and ACCP.
My vision for the community is for all members to be fully engaged in utilizing the discipline of Pharmacometrics for making impact within their organizations, and I have demonstrated my commitment toward this vision through leadership activities that focused on identifying opportunities for pharmacometricians to have a greater impact on the drug development process. I would like to highlight the following skills and leadership activities that demonstrate my ability to contribute to ISoP:

1) I have contributed consistently to the ISoP community through organization of key scientific programming at ACoP annual meetings
    a. I organized the opening session at the 2013 annual meeting,
    b. the Open Forum on extrapolation of efficacy from adults to children at the 2014 annual meeting,
    c. a key session on the role of big data in drug development at the 2015 annual meeting.
    d. I am currently organizing a tutorial session on the role of pharmacometrics in benefit-risk assessments for the 2019 annual meeting.
2) My related past leadership in the modeling and simulation community at AAPS where
    a. I chaired the erstwhile modeling and simulation focus group, and then led its reorganization to create the first pharmacometrics focus group at AAPS. I co-chaired the focus group for the first 2 years and was successful in recruiting committed community members to create an active organization that extensively engaged the pharmacometrics community via webinars and annual meeting programming.
    b. I subsequently served AAPS as the chair of the Clinical Pharmacology and Translation Research section, where I continued to advocate for pharmacometrics, both as a discipline and community, via my role in selection on annual meeting programming and recognition of significant scientific contributors (including students) within the community;
3) My ability to effectively communicate both within and outside the pharmacometric community, based my extensive experience in the strategic aspects of drug development in a large company. The unique skills of communicating with various stakeholders, whether statisticians, clinicians, regulators, or governance, is critical for influencing stakeholders to increase the impact of our discipline, and I believe these skills would add to the impact I can have as a member of the ISoP Board.

If elected to the Board, I look forward to serving ISoP by fostering increased collaboration and interaction between stakeholders, such as related scientific organizations, regulatory agencies, and industry to identify and fully leverage opportunities and initiatives (e.g, the MIDD initiative at FDA)

that have the potential to increase the impact of pharmacometrics in drug development. While pharmacometrics is now integral to the drug development and registration process, I do think that our community need to continue on the path of integration and acceptance into the entire medicine lifecycle. This path includes further definition of the role of MIDD in the drug development and approval phase by engagement of stakeholders, as well as the identification of opportunities to make in-roads in newer frontiers such as real-world data utilization and pharmacoeconomics. An additional objective is to initiate a discussion on the potential for process automation in pharmacometrics and its role in resource management, to address the need to standardize processes and resource models to respond effectively in a data-driven world.

Thank you for your kind consideration!

Arnab Mukherjee, PhD

Clinical Pharmacology, Global Product Development

Pfizer Inc,

Groton, CT 06340