Pharmacometrics 2020

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Objectives: The goal of the presentation is to share our vision for the future

Between 2000-2007 FDA Pharmacometrics group reviewed 140 NDAs, 250 QT reports/protocols and several pilot EOP2A meetings and was involved in disease model development. The impact of our regulatory reviews was documented by conducting customer surveys. About 85% of our reviews translated into important regulatory decisions pertaining to drug approval and labeling. Proficiency in both technical and soft (negotiation, presentation, strategy) skills drove this success. The increasing demand for this type of work calls for improving the efficiency with which we perform and report these analyses. There is an urgent need for us to strategize on integrating Pharmacometrics with the drug development process. Academia, industry and regulatory scientists have equal but different roles to play in this transformation. Challenges (or opportunities) and potential solutions to take the field of Pharmacometrics (or Quantitative Clinical Pharmacology) to the next level will be presented.

References: