ASCPT

FROM MOLECULE TO PATIENT

ASCPT 2019 ANNUAL MEETING

FROM MOLECULE TO PATIENT

2019 Sheiner-Beal Pharmacometrics Award

Jogarao Gobburu, PhD, MBA, FCP, FISoP

Joga Gobburu, PhD, MBA, FCP, FISoP

FDA Service

FROM MOLECULE TO PATIENT

- 1999: Pharmacometrics Reviewer
- 2002: Team Leader, Pharmacometrics
- 2007: Established the FDA Division of Pharmacometrics
- 2007-2011: Director, Division of Pharmacometrics (DPM)
- 2010-2011: Team Leader, Psychiatry, Office of Clinical Pharmacology

FROM MOLECULE TO PATIENT

Joga Gobburu, PhD, MBA, FCP, FISoP

Regulatory Contributions to Pharmacometrics

FROM MOLECULE TO PATIENT

- Assessed 250 New Drug, Biologic Licensing Applications, 250 Clinical Trial Protocols
- Extensive Contributions to Policy Development
  - Population PK, Exposure-Response, QT Studies, End of Phase 2A Meetings, Clin Pharm Considerations for Pediatric Drug Development, Approval Criteria for Parkinson's disease-modifying claim, Regulatory expectations on use of Pharmacometric software
- Transformed FDA's Pharmacometrics Program:
  - 'Pharmacometrics 2020'
  - Developed 25 scientific leaders
  - Established sustainable fellowship program (15 fellows)
  - Pioneered IT-based strategic solutions
  - Documented and disseminated the value of pharmacometrics in drug development and regulatory decision making via 70+ publications including the 'FDA Impact' series

Joga Gobburu, PhD, MBA, FCP, FISoP

Current Role

- Professor & Executive Director, Center for Translational Medicine, School of Pharmacy, School of Medicine, University of Maryland
  - First ever 100% online Executive Master's program in Pharmacometrics
  - Scientific, technical, and soft skills
  - Over 100 past and current students

  - 30+ publications
  - Numerous collaborations:
    - UCSF - pediatrics initiative
    - MIT - Artificial Intelligence & Machine Learning for Decision Support Systems

Joga Gobburu, PhD, MBA, FCP, FISoP

Scientific Contributions

FROM MOLECULE TO PATIENT

- Pharmacometric pioneer with outstanding achievements at the forefront of leadership in pharmacometrics over 15+ years
  - Executing on his vision by advancing the discipline through impact on regulatory evaluation, improving operational efficiency, public health advantage, and pharmaceutical R&D productivity
  - Cutting edge applied research and training of outstanding current and future scientific leaders in pharmacometrics
  - Leading a transformative change in pharmacometrics from a virtually incomprehensible and complex multidisciplinary science into a vital and integral decision-supporting science

FROM MOLECULE TO PATIENT

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