

A 3D molecular model composed of various colored spheres (blue, green, red, orange, yellow, pink, white) connected by thin white rods, set against a light blue background. A faint, light blue silhouette of a human head is visible behind the model. The text "FROM MOLECULE TO PATIENT" is overlaid on the right side of the image.

FROM
MOLECULE TO
PATIENT

ASCPT 2019
ANNUAL MEETING



2019 Sheiner-Beal Pharmacometrics Award

Jogarao Gobburu, PhD, MBA, FCP, FISoP

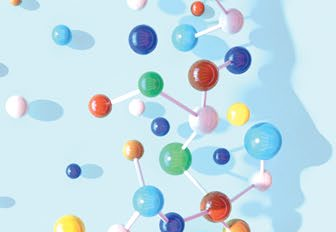


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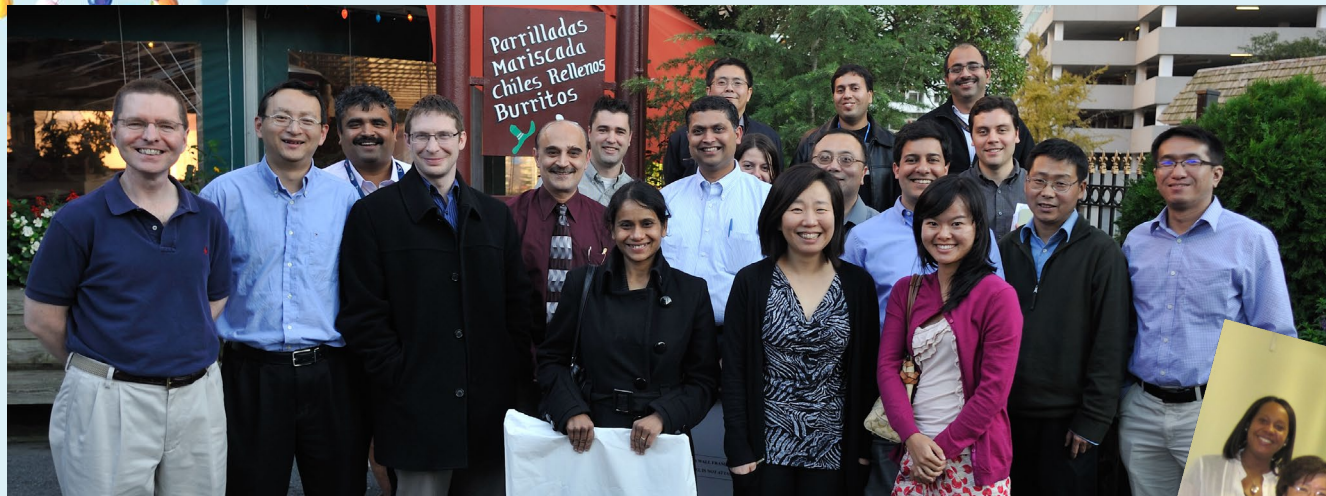
FDA Service

FR
M
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



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Regulatory Contributions to Pharmacometrics

- 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



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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

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Scientific Contributions

- 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



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