JEFF **BARRETT**

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SUMMARY

Solution-oriented, collaborator and leader - I'm very focused on continued learning to "know the unknowable" and am a versatile, creative and open-minded problem solver.

SKILLS

- Experienced team builder and hands-on quantitative scientist
- Creative visionary for model-informed drug development
- Demonstrated collaborator with various technologies to inform pediatric research and development

EXPERIENCE

04/2018 to Current **Head, Quantitative Sciences**

Bill & Melinda Gates Medical Research Institute – Cambridge, MA

- Implementing model-based drug development and employing PK/PD modeling, statistics, and clinical trial simulations to advance the discovery and development of new medicines and vaccines to treat malaria, tuberculosis (TB) and enteric diarrheal disease (EDD).
- Provides support for other Institute efforts requiring development/quantitative support including vector control, diagnostics, and product development.
- Engaging and leading the Global Health Ecosystem in the promotion of Open Science policies to create a collaborative for data and model sharing.
- Participates in the decision making and overall operations of the Institute and helps to build the new organization including modeling and driving the desired culture, hiring individuals with the talent, drive, and skills to achieve the Institute mission, and providing input on systems and the overall operating model. Building and managing a team responsible for establishing the modeling, biostatistics, bioinformatics, and DMPK function for the Institute.

12/2013 to 04/2018 **Vice President, Translational Informatics**

Sanofi Pharmaceuticals – Bridgewater, NJ

- Translational Informatics (TI) comprised Quantitative Systems Pharmacology, Bioinformatics & Data Integration, Drug-disease modeling and Clinical Trial Simulation groups within Sanofi. The global group includes 34 quantitative scientists that participate in various aspects of model-based decision-making spanning from drug discovery through commercialization. The group is positioned to provide strategic guidance to project teams and various decision-making bodies as well as senior management.

- Leadership for R&D's cloud-based, high-performance computing and big data and RWE initiatives provided in collaboration with IS and IT and external technology partners.
- The Global Head of Pediatric Clinical Pharmacology role provided support to all pediatric clinical development plans and regulatory filing strategy. The co-leadership of the Sanofi Pediatric Network advises project teams on design, conduct and analysis. External advisory roles on the International Neonatal Consortium (INC) and as the PhRMA Topic Lead for E11A (Pediatric Extrapolation).

05/2011 to 11/2013 **Professor, Pediatrics**

University Of Pennsylvania Medical School – Philadelphia, PA

- Principal Investigator for the CHOP Pediatric Pharmacology Research Unit and the Director of the Penn/CHOP Kinetic Modeling and Simulation core.
- Research was focused on the investigation of sources of variation in pediatric pharmacokinetics. Applied clinical pharmacologic investigation coupled with modeling and simulation strategies are pursued to develop rational dosing guidance in various pediatric and adult populations for both marketed and exploratory compounds. Clinical trial simulation is utilized prospectively to explore design dependencies and parameter sensitivities. Funding provided for 12 staff members from U01, U19, P01, LLS and R01 NIH grants.
- The Laboratory for Applied PK/PD was focused on the development of novel pharmacometric approaches, biomarker development, medical informatics and disease progression modeling.
- Pioneered the integration of model-based decision support systems with hospital electronic medical records.
- Development of disease progression models for spinal muscular atrophy (SMA) and pancreatic cancer; model-based development approaches for Traditional Chinese Medicine (TCM) and gene therapy were also in development.

04/2003 to 05/2011 **Associate Professor, Pediatrics**

University Of Pennsylvania Medical School – Philadelphia, PA

04/2001 to 04/2003 **Head, Global Biopharmaceutics**

Aventis Pharmaceuticals – Bridgewater, NJ

- Managed 13 scientists worldwide to support late stage development (Phase IIb through post marketing) with an annual budget of $25 million Euro.
- Responsibilities included the conduct and regulatory submission preparation of definitive clinical bioavailability and bioequivalence and related manufacturing specification studies, formulation development and screening trials, population pharmacokinetics, late stage drug interaction and special population studies, population PK/PD and mechanistic PK characterization.

- Represented core activities on both Leads Optimization (LO) and Product Realization (PR) leadership teams, the PR operating review committee, and various global pharmacokinetics methods coordination teams.
- Co-chaired DMPK-IS Data Warehouse and Modeling & Simulation project teams. Steering Committee member for Modeling & Simulation effort.
- Provided leadership and guidance on pharmacometrics functions for global regulatory submissions.

11/2000 to 04/2001 **Director, Clinical Pharmacokinetics**
DuPont Pharmaceuticals – Newark, DE

- Directed the Clinical PK effort in support of the cardiovascular and CNS franchises as well as the IT support of the DM&PK department. Conduct preclinical and clinical aspects of drug development including bioanalytical, toxicokinetic, pharmacokinetic, and pharmacodynamic support. Functional responsibilities include protocol design, toxicokinetic, pharmacokinetic, pharmacodynamic analyses and reporting for pre-NDA and NDA development stages, FDA liaison, and bioanalytical site selection. Supervisory responsibilities included the management of 3 PhD scientists, 1 web-programmer, 1 data warehouse administrator, and 2 junior staff scientists.
- Co-authored population pharmacokinetic analysis reports for Sustiva and innohep NDAs. Co-authored Biopharmaceutics Sections for Morphine Sulfate CR ANDA and innohep NDA. Initiated data warehousing efforts for department including intranet-based access and exploitation tools. Developed novel biomarkers for Factor Xa inhibitor program. Company representative for co-development of SAS PH-Kinetics non-compartmental pharmacokinetic analysis application. Departmental representative for R&D Bioinformatics initiative.

08/1999 to 11/2000 **Senior Investigator**
DuPont Pharmaceuticals – Newark, DE

09/1996 to 08/1999 **Principal Research Scientist**
DuPont Pharmaceuticals – Newark, DE

03/1994 to 09/1996 **Director, Pharmacokinetics and Computer Resources**
Somerset Pharmaceuticals – Tampa, FL

- Conducted preclinical and clinical aspects of drug development, contracted all bioanalytical and clinical services, supervised database management of post marketing and ongoing clinical drug safety surveillance programs, developed flexible data entry system for monitoring of clinical laboratory and adverse event data from ongoing development programs, and provide hardware and software support for the Somerset PC network. Functional responsibilities included protocol design, study monitoring, toxicokinetic, pharmacokinetic, pharmacodynamic and statistical analyses and reporting, FDA liaison, clinical and bioanalytical site selection, the management of all R&D computer

resources, and supervision of six people (pharmacokineticist, statistician, programmers, CRAs).

- Completed numerous Phase-I studies in healthy male volunteers, healthy elderly men and women, post-menopausal women, and SDAT patients in support of the selegiline transdermal system and ipriflavone development programs and product line extensions for Eldepryl. Authored Biopharmaceutics Section for Eldepryl Capsule ANDA. Designed and completed acute, subacute and chronic toxicology studies, in vitro topical metabolism, and pharmacology studies in support of the selegiline transdermal system and ipriflavone development programs.

08/1990 to 03/1994 **Senior Research Pharmacokineticist**
Merck Research Laboratories – West Point, PA
Conducted the human aspects of ethical drug development in areas of metabolism, pharmacokinetics, pharmacodynamics, and bioanalysis in MRL Drug Metabolism Department. Responsible for fibrinogen receptor antagonist, oxytocin antagonist, growth hormone secretagogue programs, defense of Vasotec® and Pepcid® AC product lines. Co-author of Pepcid® AC NDA. Co-author of NM-Win© algorithm (front-end to NONMEM). Founded Mid-Atlantic Population Approach Methods Users Group.

EDUCATION AND TRAINING

06/1990 **Ph.D.**: Pharmaceutics
University of Michigan - Ann Arbor – Ann Arbor, MI

06/1986 **Bachelor of Science**: Chemical Engineering
Drexel University – Philadelphia, PA

ADDITIONAL ACCOMPLISHMENTS

- 167 peer-reviewed scientific publications (available upon request)
- 16 published book chapters
- Editor for textbook on Fundamentals of Drug Development (Wiley, 2021)
- Co-inventor of Image Analysis for Predicting Body Weight in Humans patent
- co-Specialty Chief Editor of Frontiers in Obstetric and Pediatric Pharmacology Journal

SQUASH FANATIC, SPORTSMAN AND ARTIST

- PSRA League member for 8 years (4.0 singles and 4.5 doubles player)
- Trout and bass fisherman
- Sculptor and painter