Ashwin Raghunath Karanam

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EDUCATION

University of Minnesota, College of Pharmacy   Minneapolis, MN
Ph.D., Experimental and Clinical Pharmacology   Expected December 2020
Pharmacometrics major with Biostatistics minor

Manipal University   Karnataka, India
Doctor of Pharmacy (PharmD)   August 2015

POSITIONS/EMPLOYMENT

RESEARCH POSITIONS

University of Minnesota, Minneapolis, MN
Graduate Research Assistant with **Dr. Angela Birnbaum**   *September 2016 – Present*
Focus: Using pharmacometric approaches to understand pharmacokinetics of antiepileptics in special populations

- My main thesis project involves using pharmacometric approaches to understand antiepileptic drug pharmacokinetic changes occurring during pregnancy, postpartum and breastfeeding infants to optimize therapy. My thesis involves several sub projects:
  o Developing population PK-PD models for understanding time varying PK changes of AEDs during pregnancy and their relationship to seizure outcomes. This has given me hands on experience with PK-PD model development and evaluation in a large observational clinical trial data (MONEAD) using NONMEM
  o Developing a dosing algorithm for AEDs in pregnancy and postpartum using stochastic simulation and estimating methods, primarily Monte Carlo simulation techniques
  o Developing a versatile breastfeeding PBPK model in mrgsolve for predicting lamotrigine exposure in infants from breastfeeding
- Non-thesis related projects include:
  o Using pharmaco-statistical approaches to characterize food effect on cannabidiol PK in adult epilepsy patients
  o Modeling pharmacokinetics of bupivacaine in breastmilk to understand relative infant dosing
  o Developing a population PK-PD model for tacrolimus in pediatric bone marrow and solid organ transplants
  o Characterizing pharmacokinetic changes of Trikafta (Elexacaftor + tezacaftor + ivacaftor) during pregnancy

GlaxoSmithKline, Collegeville, PA
Clinical Pharmacology, Modeling and Simulation Intern with **Dr. Navin Goyal**   *May 2019 – August 2019*
Focus: Using pharmacometric approaches to build exposure response relationship for a new anti-malarial drug

- Developed a population logistic regression model in NONMEM for understanding relationship between tafenoquine exposure and malaria relapse rates using data from 3 pivotal studies
- Developed a population time-to event model in NONMEM for understanding effect of exposure on time to malaria relapses using data from 3 pivotal studies
- Developed population pharmacokinetic model for a selective estrogen receptor modulator using circadian rhythm patterns for binding of drug and receptor

Advanced Centre for Treatment, Research and Education in Cancer, India
Pharmacometrics Research Fellow with **Dr. Vikram Gota**   *January 2016 – August 2016*
Focus: Using pharmacometric approaches to optimize and individualize therapy in oncology
- Used Population PK approaches to establish bioequivalence of a rituximab biosimilar
- Developed a pharmacometric model of paclitaxel to analyze effect of BMI on exposure
- Used stochastic simulation techniques for pediatric voriconazole dose optimization
- Used D-optminal sampling to develop and initiate a study to characterize colistin PK in bone marrow transplant patients

Manipal ACUNOVA, India
Bioanalytical Intern with **Dr. Vasudev Shenoy**   *January 2016 – August 2016*
Focus: Development and validation of bioanalytical methods on chromatographic/mass spectroscopic systems
- Method development and validation of protein-based drugs especially insulin analogues
- Developing and maintaining method standard operating procedures

CLINICAL POSITIONS

Kasturba Medical College, Manipal Hospitals, India
Clinical Pharmacy Resident with **Dr. Suriliveil Rajan**   *February 2015-August 2015*
- Rotations in Medicine, Surgery and Psychiatry
- Provided Clinical Counseling and prescription reviews
- Part of the Adverse Drug Review detection team reporting ADRs and AEs for pharmacovigilance

TEACHING POSITIONS

Teaching Assistant, University of Minnesota, College of Pharmacy
- PHAR 7421, Elective Practice Experience 1   *Fall 2016*
- PHAR 6784, Integrated Oncology   *Spring 2017, and Spring 2018*

REAEARCH AND TECHNICAL SKILLS

1. Pharmacometrics skills:
   - Population PK-PD modeling with NONMEM (Pirana and PDx-Pop GUI), Pumas and Phoenix NLME
   - Physiology-based PK modeling with SimCyp
   - Dynamic simulations with mrgsolve, Pumas and Berkeley-Madonna
   - Phoenix BE, NCA, Compartment models, IVIVC and IVIVE plugins
2. Programming skills:
   - Data wrangling and complex function building in R, Julia and Python with a pharmacometric focus
   - Experience with dynamic model building using mrgsolve (R package), MATLAB, and Berkeley-Madonna
   - Dataset and version control experience with GitHub and GitKraken
3. Biostatistics skills:
   - Design and implement statistical / predictive models in R for with focus on longitudinal data and complex pharmaco-statistical analysis
   - Experience with SPSS and Graph Pad
4. Bioanalytical skills:
   - Liquid Chromatography – Mass Spectroscopy
   - High Performance Liquid Chromatography

5. Clinical Research Skills: Trained in
    - Design and implementation of clinical pharmacology trials
    - ICH-GCP and HIPAA trained

HONORS AND AWARDS

- Elected as Chair of ISoP Student Community *2020 - Present*
- University of Minnesota Doctoral Dissertation Fellowship *2019-2020*
- Elected as Trainee Chair for 10th American Conference on Pharmacometrics *2019-2020*
- Elected as University of Minnesota representative for International Society for Pharmacometrics Student Leadership Team *2016-2020*
- Tata Memorial and Advanced Centre for Treatment, Research and Education in Cancer Research Fellowship in Pharmacometrics and Clinical Pharmacology *2016*
- Australia and Asia Pacific Clinical Oncology Research Development (ACORD) fellowship *2016*
- *Summa Cum Laude*, PharmD Class of 2016, Manipal University *2016*
- Dean's List for First Class with Distinction, Manipal University *2010-2016*

PUBLICATIONS

Original Research:

1. Mustafa HJ, Wong HL, Al-Kofahi M, Schaefer M, **Karanam A**, Todd MM. Bupivacaine Pharmacokinetics and Breast Milk Excretion Following Liposomal Bupivacaine use in Cesarean Birth. *Obstetrics & Gynecology*. July 2020 - Volume 136 - Issue 1 - p 70-76. https://doi.org/10.1097/AOG.0000000000003886

2. Birnbaum AK, Meador K, **Karanam A**, Brown C, May RC, Gerard EE, Gedzelman E, Penovich P, Kalayjian LA, Cavitt J, Pack A, Pennell PB, for the MONEAD Investigator Group. Antiepileptic Drug Exposure in Infants of Breastfeeding Mothers with Epilepsy. *JAMA Neurol.* Published online December 30, 2019. https://doi.org/10.1001/jamaneurol.2019.4443

3. Birnbaum AK*, **Karanam A***, Marino SE, Barkley CP, Remmel RP, Roslawski M, Gramling-Aden M, Leppik IE. Food Effect on Cannabidiol pharmacokinetics in Adult Patients with Refractory Epilepsy. *Epilepsia.* 2019 Aug;60(8):1586-1592. https://doi.org/10.1111/epi.16093. *Co-first authors.

4. Roslawski M, Remmel RP, **Karanam A**, Leppik IE, Marino SE, Birnbaum AK. Simultaneous quantification of thirteen cannabinoids and metabolites in human plasma by liquid chromatography tandem mass spectrometry in adult epilepsy patients. *Ther Drug Monit.* 2018 Dec 4. https://doi.org/10.1097/FTD.0000000000000583

5. **Karanam A**, Pennell PB, French JA, Harden CL, Allien S, Lau C, Barnard S, Callisto SP, Birnbaum AK. Lamotrigine clearance increases by 5 weeks gestational age: Relationship to estradiol concentrations and gestational age. *Ann Neurol*. 2018 Oct;84(4):556-563. https://doi.org/10.1002/ana.25321

6. Kulkarni P, **Karanam A**, Gurjar M, Dhoble S, Naik AB, Vidhun BH, Gota V. Effect of various anticoagulants on the bioanalysis of drugs in rat blood: implication for pharmacokinetic studies of anticancer drugs. *Springerplus*. 2016 Dec 20;5(1):2102. https://doi.org/10.1186/s40064-016-3770-4

7. Punniyakotti N, Prasad HB, Reddy UM, Hiremath SR, Rajan SM, **Karanam A**. Population Pharmacokinetics of Doxophylline In Bronchial Asthma Patients. *World J Phar and Life Sci*. 2016 Aug; 2(4):319-332.

8. Gota V, **Karanam A**, Rath S, Yadav A, Tembhare P, Subramanian P, Sengar M, Nair R, Menon H. Population pharmacokinetics of Reditux™, a biosimilar Rituximab, in diffuse large B-cell lymphoma. *Cancer Chemother Pharmacol*. 2016 Aug;78(2):353-9. https://doi.org/10.1007/s00280-016-3083-x

Case Studies:

1. Singh A, Khera K, **Karanam A**, Chauhan S. Job's syndrome in a pediatric patient: Case report and the clinical review. *Indian Journal of Paediatric Dermatology*. 2015; 16:96-8. https://doi.org/10.4103/2319-7250.152133
2. Singh A, Khera K, **Karanam A**, Chauhan S, Rana R. Neuro-ophthalmic complications in systemic lupus erythematosus: Case analysis and the literature review. *International Journal of Biomedical Research*. 2015; 6(06): 435-438. https://doi.org/10.7439/ijbr.v6i6.1882
3. Suraj DJ, Singh A, **Karanam A**, Khera K, Rana R, Hande MH. Clinical Course and Management of Iatrogenic Cushing's Syndrome in A Post Splenectomy Evans Syndrome Patient. *International Journal of Healthcare Sciences*. 2014; 2(1):156-158.

Review:

1. Illamola SM, Amaeze OU, Krepkova LV, Birnbaum AK, **Karanam A**, Job KM, Bortnikova VV. Use of Herbal Medicine by Pregnant Women: What Physicians Need to Know. *Front Pharmacol*. 2020;10:1483. 2020 Jan 9. https://doi.org/10.3389/fphar.2019.01483

PRESENTATIONS

Webinar

1. "Tutorial on Bioequivalence Using Phoenix" for Experimental and Clinical Pharmacology Pharmacometrics Webinar Series sponsored by Certara. April 2017.

External: International

1. "Cannabinoids in modern medicine". Jan 2019. Invited talk at Advanced Centre for Treatment, Research and Education in Cancer, Mumbai, India; Invited Seminar
2. "Large Molecule Pharmacokinetics: Antibodies and ADCs". Dec 2018. Invited talk at Advanced Centre for Treatment, Research and Education in Cancer, Mumbai, India; Invited Seminar
3. "Physiology-based Pharmacokinetic Models and why you should be using them". Dec 2017. Invited talk at Advanced Centre for Treatment, Research and Education in Cancer, Mumbai, India; Invited Seminar
4. "Effect of body mass index on pharmacokinetics of paclitaxel in women with early breast cancer". Oct 2016. European Society of Medical Oncology Annual Conference. Copenhagen, Denmark; Abstract available at https://doi.org/10.1093/annonc/mdw364.48; Poster
5. "Population pharmacokinetics of Reditux™, a biosimilar Rituximab, in diffuse large B-cell lymphoma". Aug 2016. World Conference on Pharmacometrics. Brisbane, Australia; Poster

External: National

1. "Empiric lamotrigine dosing strategies during pregnancy: A simulation study". Dec 2018. American Epilepsy Society Annual Meeting. New Orleans; Poster and Platform
2. "A PBPK Model for Drug Exposure of Lamotrigine in Breastfed Infants". Oct 2018. American Conference on Pharmacometrics. San Diego; Poster
3. "Relationship of Estradiol and lamotrigine clearance during pregnancy is detectable within the first trimester". Dec 2017. American Epilepsy Society Annual Meeting. Washington, DC; Poster
4. "Food effect on Cannabidiol Pharmacokinetics in adult refractory epilepsy patients". Dec 2017. American Epilepsy Society Annual Meeting. Washington, DC; Poster

Internal: University of Minnesota

1. "Food effect on Cannabidiol Pharmacokinetics in adult refractory epilepsy patients". College of Pharmacy Research Day – Spring 2019; Poster

2. "A PBPK Model for Drug Exposure of Lamotrigine in Breastfed Infants". College of Pharmacy Research Day – Spring 2019; Poster
3. "Food effect on Cannabidiol Pharmacokinetics in adult refractory epilepsy patients". Board of Advisors Reception – Fall 2018; Poster
4. "Food effect on Cannabidiol Pharmacokinetics in adult refractory epilepsy patients". ECP Graduate Seminar – Spring 2018: Oral
5. "Effect of body mass index on pharmacokinetics of paclitaxel in women with early breast cancer". ECP Graduate Seminar – Spring 2017: Oral

WORKSHOPS

1. Pumas DDMoRe Bootcamp by The Pumas Development Team – Summer 2020
2. Bayesian modeling in NONMEM by MetrumRG at ACoP10 – October 2019
3. Quantitative Systems Pharmacology in Drug Development at ACoP10 – October 2019
4. TACA Pharmacometrics Workshop by Adrian Dunne at Ireland – October 2019
5. Simcyp 3-day workshop by Simcyp – March 2019
6. Role of Pharmacometrics in first-in-human trials at ACoP9 – October 2018
7. mrgsolve Workshop by Kyle Baron at University of Minnesota – December 2017
8. Introductory NONMEM workshop at ACTREC, India – May 2016
9. Phoenix NLME workshop by Serge Guzy at ACTREC, India – October 2015
10. Gastroplus workshop by Gastroplus at Coimbatore, India – August 2015

RELATED PROFESSIONAL EXPERIENCE

International Society of Pharmacometrics, Student Community
Chair   *January 2020 – Present*
- Led the ISoP Student Community. Instrumental in growing the student community, bringing in international visibility, and launching the stand-alone website for the community.

Steering Committee Member   *2017 – 2019*
- Collaborate with students across the globe to develop educational opportunities related to pharmacometrics for ISoP student community

International Society of Pharmacometrics, Publications Committee
Student Representative   *February 2017 – Present*
- Developed and published the first ISoP newsletter.
- Working on releasing newsletter quarterly, with plans to improve student research dissemination.

Population Approach Group of India, Coordination Committee
Member   *2014 –2016*
- Organized PAGIN Gastroplus workshop at PSG medical school, Coimbatore, 3rd-5th February 2016
- Organized Workshop on 'PK/PD Modeling' at Tata ACTREC at Kharghar, Mumbai, 8th -10th October 2015 lead by Dr. Navin Goyal (GSK) and Dr. Ayyappa Chaturvedula (UNT)
- Organized PAGIN NONMEM workshop at PSG medical school, Coimbatore, 15th-18th December 2014

PROFESSIONAL ASSOCIATIONS

- International Society of Pharmacoeconomics and Outcomes and Research   *2010-2014*
- Population Approach Group of India   *2014-Current*
- International Society of Pharmacometrics   *2016-Current*
- American Epilepsy Society   *2017-Current*
- American College of Clinical Pharmacology   *2020-Present*