

BIOGRAPHICAL SKETCH

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NAME: **Mahesh Kudrimoti, MD**

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Professor, Radiation Medicine; Co-Chair Clinical Operations; Residency Program Director

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Little Flower Junior College, Hyderabad, India	BS	06/1986	Biology, Physics, Chemistry
Osmania Medical College, Hyderabad, India	MD, MBBS	06/1992	Medicine
Post Graduate Institute of Medical Education and Research, Chandigarh, India		06/1996	Resident, Radiation Oncology
Robert Packer Hospital, Sayre, PA		06/1997	Intern, Surgery
University of Kentucky, Lexington, KY		06/2001	Resident, Radiation Oncology

A. Personal Statement

I have trained as a Radiation Oncologist since 1993. My initial training was in India which has a high incidence of Head and neck cancer cases diagnosed in advanced stages. I have continued to focus my practice in Head and Neck cancer cases after joining University of Kentucky in 2001 as Assistant Professor. During the past 15 years I have participated in several investigator-initiated, industry sponsored and intergroup trials focusing on the advancement of treatment strategies in Head and Neck cancer. I have participated in several trials designed for mucositis attenuation. Mucositis is a very common problem with no adequate measures to attenuate the quality of life experienced by the patients. I have been a part of a mucositis study group and we have published our experience in peer reviewed journals. I have also been the Clinical PI on NIH funded studies and other grants in Head/Neck cancers. As of this time we are involved in at least 4 active clinical trials in Head/Neck cancer. I am involved in clinical research, teaching and administration.

B. Positions and Honors**Positions and Employment**

2001-2006 Assistant Professor, Department of Radiation Medicine, University of Kentucky
 2006-2013 Associate Professor, Residency Program Director, Department of Radiation Medicine, University of Kentucky
 2013-present Professor, Vice-Chair for Clinical Operations, Residency Program Director, Department of Radiation Medicine, University of Kentucky

Honors

1984 National Merit Scholarship by the Government of India for excellence in the Class X Examinations
 1986 National Merit Scholarship by the Government of India for excellence in the Class XII Examinations
 1989 "Distinctions"- Honors for securing more than 75% marks at the examinations and being among the top 1% among 350 medical students in the field of Microbiology and Pharmacology examinations
 1990 Highest marks in the field of Otolaryngology at the Final Medicine examinations (Top 1% of the University)

- 1991 Highest Marks in the field of Internal Medicine at the Final Medicine Examinations (Top 1% in the University)
- 1992 “Best out-going student” in the batch of Medical Students joining the Osmania Medical College in the Year 1986
Bhagwan Satya Sai Baba Gold medal awarded by Sai Prashanti Society for Excellence in the Field of Medical, Dental, Veterinary and Agricultural Sciences in the state of Andhra Pradesh by the Governor of Andhra Pradesh
- 1994 Dr Neals Travelling Fellowship awarded at the XV Annual Association of Radiation Oncologists of India Congress at Jamshedpur, India, January 7-9
Harish N Kulkarni Innovative Paper presentation award on “Cerebral metastasis in breast cancer” at the XV Association of Radiation Oncology congress from Jan 7-9, 1994 at Jamshedpur, India.
- 1997 ASTRO - ANNA HAMANN International Fellowship awarded by the American Society for Therapeutic Radiology and Oncology (ASTRO)
- 2000 Roentgen Resident / Fellow Research Award by the Radiological Society of America (RSNA)
Chief Resident, Department of Radiation Medicine, University of Kentucky
- 2007-2010 ARRO Teacher of the Year Award
- 2011 ARRO Educator of the Year Award
- 2012 Abraham Flexner Master Educator Award in Teaching, Leadership & Innovation
- 2014 Scientific recognition of Best of ASTRO presentations of University of Kentucky Experience in head/neck cancers
- 2009-2014 Peer nominated to Best Doctors in America
- 2011-2015 Peer nominated Castle Connolly/US News Report Top Doctor in Cancer

C. Contributions to Science

1. **Development of treatment techniques and strategies for Head Neck Cancer.** I have been involved with the development of newer techniques and management strategies for head and neck cancer since joining the field of Radiation Oncology in 1992. My preliminary experience was in India which has a high incidence of oral cancers and other head and neck cancers. I have been involved as an institutional principal investigator in several trials of national interest such as the RTOG, ECOG, SWOG trials. These trials have focused on the development of new fractionation schemes and dose alterations in p16 positive tumors. Trans oral robotic surgery experience is one of the key advancements made over the past 10 years in oropharyngeal cancers.
 - a. Fakhry C, Zhang Q, Nguyen-Tân PF, Rosenthal DI, Weber RS, Lambert L, Trotti AM 3rd, Barrett WL, Thorstad WL, Jones CU, Yom SS, Wong SJ, Ridge JA, Rao SSD, Bonner JA, Vigneault E, Raben D, **Kudrimoti MR**, Harris J, Le QT, Gillison ML. Development and Validation of Nomograms Predictive of Overall and Progression-Free Survival in Patients With Oropharyngeal Cancer. *J Clin Oncol* 35:4057-4065, 2017. PMID: PMC5736236
 - b. Gal TJ, Streeter M, Burris J, **Kudrimoti M**, Ain KB, Valentino J. Quality of life impact of external beam radiotherapy for advanced thyroid carcinoma. *Thyroid* 23:64-69, 2013.
 - c. Valentino J, Helton WB, Unnikrishnan R, **Kudrimoti M**, Arnold SM, Gal TJ. Microvascular reconstruction after intra-arterial chemotherapy with concomitant radiation. *Otolaryngol Head Neck Surg* 149:541-546, 2013.
2. **Predictive technology development.** Predicting response rates to therapy has always been a focus of much research and frustration. Cancer prediction models have, at best, been most unpredictable. I have collaborated with biomechanical engineers to develop a novel mechanism using a non invasive optical diffusion probe to predict outcomes for head and neck cancer. The project has been funded by NIH as a R01 study and is up for renewal.
 - a. Dong L, **Kudrimoti M**, Cheng R, Shang Y, Johnson EL, Stevens SD, Shelton BJ, Yu G. Noninvasive diffuse optical monitoring of head and neck tumor blood flow and oxygenation during radiation delivery. *Biomed Opt Express* 3:259-272, 2012. PMID: PMC3269843

- b. Dong L, **Kudrimoti M**, Irwin D, Chen L, Kumar S, Shang Y, Huang C, Johnson EL, Stevens SD, Shelton BJ, Yu G. Diffuse optical measurements of head and neck tumor hemodynamics for early prediction of chemoradiation therapy outcomes. *J Biomed Opt* 21:85004, 2016. PMID: PMC4999482

3. Mucositis management. One of the most distressing side effects of head and neck irradiation is mucositis. I have been the principal lead investigator in the use of Dusesquetide, a novel small molecule, in alleviating mucositis. The trial has been published in the *Journal of Biotechnology* as a Phase II trial and Phase III studies are underway. This is industry sponsored research. There is currently no FDA-approved drug for Mucositis.

- a. Elting LS, Keefe DM, Sonis ST, Garden AS, Spijkervet FK, Barasch A, Tishler RB, Canty TP, **Kudrimoti M**, Vera-Llonch M, Burden of Illness Head and Neck Writing Committee. Patient-reported measurements of oral mucositis in head and neck cancer patients treated with radiotherapy with or without chemotherapy: demonstration of increased frequency, severity, resistance to palliation, and impact on quality of life. *Cancer* 113:2704-2713, 2008.
- b. Randall K, Stevens J, Yepes JF, Randall ME, **Kudrimoti M**, Feddock J, Xi J, Kryscio RJ, Miller CS. Analysis of factors influencing the development of xerostomia during intensity-modulated radiotherapy. *Oral Surg Oral Med Oral Pathol Oral Radiol* 115:772-779, 2013. PMID: PMC3665637
- c. **Kudrimoti M**, Curtis A, Azawi S, Worden F, Katz S, Adkins D, Bonomi M, Elder J, Sonis ST, Straube R, Donini O. Dusquetide: A novel innate defense regulator demonstrating a significant and consistent reduction in the duration of oral mucositis in preclinical data and a randomized, placebo-controlled phase 2a clinical study. *J Biotechnol* 239:115-125, 2016.
- d. **Kudrimoti M**, Curtis A, Azawi S, Worden F, Katz S, Adkins D, Bonomi M, Scott Z, Elder J, Sonis ST, Straube R, Donini O. Dusquetide: Reduction in oral mucositis associated with enduring ancillary benefits in tumor resolution and decreased mortality in head and neck cancer patients. *Biotechnol Rep (Amst)* 5:24-26, 2017.

4. Innovative Therapy. Advanced cancers often produce management dilemmas. The outcomes with standard management is often dismal. I have used several innovative methods to increase therapeutic outcomes in advanced cancers especially the head and neck cancers. These include the use of Intraarterial chemotherapy, induction therapy with low dose radiation therapy for radiosensitization, and Spatially fractionated GRID therapy for tumors more than 6 cm size. The Phase III study with low dose radiation for chemosensitization is ongoing.

- a. Gleason Jr JF, **Kudrimoti M**, Van Meter EM, Mohiuddin M, Regine WF, Valentino J, Arnold SM. Low-dose fractionated radiation with induction chemotherapy for locally advanced head and neck cancer: 5 year results of a prospective phase II trial. *J Radiat Oncol* 2:35-42, 2013. PMID: PMC4457337
- b. Arnold SM, **Kudrimoti M**, Dressler EV, Gleason JF Jr, Silver NL, Regine WF, Valentino J. Using low-dose radiation to potentiate the effect of induction chemotherapy in head and neck cancer: Results of a prospective phase 2 trial. *Adv Radiat Oncol* 1:252-259, 2016. PMID: PMC5514161
- c. Spring P, Valentino J, Arnold S, Sloan D, Kenady D, **Kudrimoti M**, Haydon R III, Lee C, Given C, Mohiuddin M, Regine W. Long-term results of hyperfractionated radiation and high-dose intraarterial cisplatin for unresectable oropharyngeal carcinoma. *Cancer* 104:1765-1771, 2005.
- d. Huhn JL, Regine WF, Valentino J, Meigooni AS, **Kudrimoti M**, Mohiuddin M. Spatially fractionated GRID radiation treatment of advanced neck disease associated with head and neck cancer. *Technol Cancer Res Treat* 5:607-612, 2006.

5. Other Cancers. I have been involved in several clinical trials and unique clinical experiences in cancers of the gastrointestinal and gynecological systems. This includes a large clinical experience in HDR brachytherapy at GI and Gyn sites and participation in several investigator and intergroup trials which have shown incremental benefits.

- a. Berk L, Berkey B, Rich T, Hrushesky W, Blask D, Gallagher M, **Kudrimoti M**, McGarry RC, Suh J, Mehta M. Randomized phase II trial of high-dose melatonin and radiation therapy for RPA class 2 patients with brain metastases (RTOG 0119). *Int J Radiat Oncol Biol Phys* 68:852-857, 2007. PMID: PMC2709786

- b. Regine WF, Winter KA, Abrams RA, Safran H, Hoffman JP, Konski A, Benson AB, Macdonald JS, **Kudrimoti MR**, Fromm ML, Haddock MG, Schaefer P, Willett CG, Rich TA. Fluorouracil vs Gemcitabine Chemotherapy Before and After Fluorouracil-Based Chemoradiation Following Resection of Pancreatic Adenocarcinoma: A Randomized Controlled Trial. JAMA 299:1019-1026, 2008.
- c. Mohiuddin M, **Kudrimoti M**, Regine W, McGrath P, Hanna N, John W. Concurrent infusional gemcitabine and radiation in the treatment of advanced unresectable GI malignancy: a phase I study. Cancer J 8:255-262, 2002.

D. Research Support

Ongoing

GT-201 (PI: Kudrimoti, M) 02/24/16-02/23/18

Galera Therapeutics Incorporated

“15-28-HN-28-GT (GT-201): A Phase 2 Randomized, Double-Blind, Placebo-Controlled, Multicenter Trial of the Effects of Intravenous GC4419 on the Incidence and Duration of Severe Oral Mucositis (OM) in Patients Receiving Post-Operative or Definitive Therapy”

Goals: Clinical trial

Role: PI

IDR-OM-01 (PI: Kudrimoti, M) 10/15/13-03/15/18

Soligenix Incorporated

“13-HN-22-SGX (IDR-OM-01) Phase 2 study of SGX942 for oral mucositis in head & neck cancer patients treated with CRT”

Goals: Clinical trial

Role: PI

P02 415 1300001126 1 (PI: Izumi, T)

07/01/14-06/30/18

Kentucky Lung Cancer Research Fund

“DNA Damage Biomarkers for Carcinogenesis Related to Tobacco Product Use”

Goal: To examine relationships between tobacco smoke exposure, induced DNA damage, and DNA damage responses in regard to development of head and neck squamous cell carcinoma.

Role: Co-Investigator

P02 415 1300001126 1 (PI: Arnold, S)

08/01/14-07/31/18

Kentucky Lung Cancer Research Fund

“A randomized phase II trial of induction chemotherapy and low-dose fractionated radiation”

Goal: To investigate the role of low-dose fractionated radiation (LDFRT) in a randomized phase II trial with induction chemotherapy in locally advanced SCCHN, with correlative evaluation of DNA repair response to different doses of radiation given to these participants.

Role: Co-Investigator